

102  
3  
5  
05-22-01  
Am

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



APPELLANTS: Cupp et al. DOCKET NO.: 0112701-021

SERIAL NO.: 09/154,646 GROUP ART UNIT: 1761

FILING DATE: September 17, 1998 EXAMINER: K. Hendricks

TITLE: "DENTAL CARE PET FOOD"

Assistant Commissioner for Patents  
Washington D.C. 20231

**APPELLANTS' APPEAL BRIEF**

Dear Sir:

This Appeal Brief is submitted in support of the Notice of Appeal submitted by Appellants on March 20, 2001 in the above-identified patent application.

RECEIVED  
MAY 25 2001  
TC 1700

**I. REAL PARTY IN INTEREST**

The real party in interest for the above-identified patent application on Appeal is NESTEC S.A. by virtue of an Assignment recorded at the United States Patent and Trademark Office.

**II. RELATED APPEALS AND INTERFERENCES**

Appellants do not believe there are any known appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

### III. STATUS OF THE CLAIMS

Claims 1-24 are pending in this Application. A copy of appealed Claims 1-24 is attached in the Appendix. In the Final Office Action dated January 2, 2001, Claims 1, 13, 20 and 24 stand rejected under 35 U.S.C. § 112, first paragraph; Claims 1-3, 6-7, 13-15 and 18-24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,743,460 ("Gellman"); and Claims 1-20 and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,407,661 ("Simone"). A copy of the Final Office Action is appended hereto as Exhibit A of the Supplemental Appendix and a copy of each of the cited references is appended hereto as Exhibits B-C of the Supplemental Appendix.

### IV. STATUS OF THE AMENDMENTS

No Amendments After Final were filed.

### V. SUMMARY OF THE INVENTION

The summary of the invention on Appeal is provided as follows:

The present invention relates generally to dry pet foods. More specifically, the present invention relates to dry pet foods which can reduce the build up of dental plaque and calculus on the teeth of pets. (Specification, page 1, lines 3-5.)

Many pets suffer from dental health problems. A primary factor in the development of these problems is a formation of plaque on the surface of the teeth. Plaque contains bacteria and other components that adhere to the surface of the teeth thereby accumulating both above and below the gum line thus leading to inflammation, gingivitis, malodors and the like in the dental cavity. (Specification, page 1, lines 9-14.)

The formation of tartar or dental calculus (mineralized plaque) is a contributing factor to the problem of plaque build up on the surface of the teeth. Dental calculus forms on the tooth surface at or above the gum line and serves as a substrate for additional accumulation of plaque. Apart from causing gum irritation and eventually periodontal disease if left untreated, the calculus has an unsightly appearance. (Specification, page 1, lines 15-19.)

Pursuant to the present invention a dry pet food is provided which can reduce the build up of dental plaque and calculus on the teeth of pets. When chewed by pets, the pet food of the present invention can cause mechanical and abrasive cleaning of the pet's teeth. (Specification, page 1, lines 3-5.) In general, the dry pet food of the present invention includes a matrix of a denatured protein source, a gelatinized carbohydrate source, insoluble fiber and a humectant in an amount sufficient for reducing brittleness of the matrix. (Specification, page 2, lines 31-34.)

Appellants have surprisingly found that the incorporation of a humectant and an insoluble fiber within a gelatinized matrix significantly reduces the brittleness of the pet food. Upon biting the pet food of the present invention, the pet's teeth can penetrate into the pet food for a longer distance prior to breaking of the pet food. In this regard, the pet's teeth can be in contact with the pet food for a longer period of time and thus are subjected to the abrasive effect of the pet food over a prolonged time period. (Specification, page 3, lines 1-6.)

The dry pet food of the present invention can also be characterized by its moisture content. In an embodiment, the moisture content of the dried pet food is less than 10% by weight.

The dry pet food of the present invention can include varying amounts and a variety of different pet food material components. For example, the matrix of the dry pet food can include at least 2% by weight of insoluble fiber, preferably about 2% to about 15% by weight of

insoluble fiber; about 0.5% to about 5% by weight of a humectant; about 12% to about 50% by weight of protein, preferably more than about 25% by weight; and about 20% to about 65% by weight of carbohydrate. (Specification, page 3, lines 8-11; page 4, lines 7-24.)

As previously discussed, the matrix component of the dry pet food, such as the denatured protein source, the gelatinized carbohydrate source, insoluble fiber and humectant, each can include a variety of different and suitable materials. In an embodiment, the humectant is glycerin. (Specification, page 4, line 34.) In another embodiment, the insoluble fiber is a cellulose fiber. (Specification, page 4, lines 26-29.)

A variety of other ingredients can also be incorporated into the dry pet food of the present invention as desired. These ingredients can include, for example, abrasive agents, salts, spices, seasonings, vitamins, minerals, flavoring agents, lipids and the like. (Specification, page 5, lines 4-12.)

The dry pet food of the present invention can also be characterized by other features, such as density, size and texture. For example, the pet food can include a density of about 250 kg/m<sup>3</sup> to about 320 kg/ m<sup>3</sup>. (Specification, page 3, lines 13-14.)

Further, the size of the pet food of the present invention can include a length of at least 6 millimeters ("mm"), a thickness of at least 6 mm and a minimum distance from a center of gravity of the matrix of the dry pet food to a surface of the matrix of about 3 mm. (Specification, page 3, lines 14-17; Specification, page 6, lines 8-20.)

The texture of the pet food of the present invention can be defined such that a probe, having a contact area of about 1 mm<sup>2</sup> and operated at a speed of about 5 mm/s, penetrates into

the matrix of the dry pet food for a distance of at least 30% of the thickness of the matrix prior to breaking of the matrix. (Specification, page 3, lines 19-24.)

The present invention provides a method of reducing calculus and plaque build up on a pet's teeth. The method includes the steps of administering to the pet a dry pet food. The dry pet food can include the same features as previously discussed. In an embodiment, the dry pet food can include a gelatinized matrix including a protein source, a carbohydrate source, an insoluble fiber source and a humectant wherein the pet food has a moisture content of less than 10% by weight and has a reduced brittleness.

As previously discussed, Appellants have surprisingly found that the incorporation of a humectant and an insoluble fiber within a gelatinized matrix significantly reduces the brittleness of the pet food. This allows the pet's teeth to penetrate into the pet food for a longer distance and over a longer period of time prior to the pet food breaking thereby facilitating the abrasive effect of the pet food on the pet's teeth for a longer period of time. In this regard, plaque build up and calculus on the pet's teeth can be effectively reduced. (Specification, page 3, lines 1-6.)

Appellants have conducted experiments to demonstrate the desirable calculus and plaque build up reducing effects of the dry pet food of the present invention. First, Appellants prepared a dry pet food illustrative of the dry pet food of the present invention. (Specification, page 7, Example 1.) The dry pet food of Example 1 included, for example, about 49% by weight of corn flour, about 19% by weight of corn gluten, about 8% by weight of fish and poultry meals, about 5% by weight of cellulose (insoluble fiber), about 2% by weight of glycerin (humectant) and various vitamins and minerals. Further, the dry pet food of Example 1 included a density of about 285 kg/m<sup>3</sup> and a moisture content of about 6.5% by weight. (Specification, page 7, Example 1.)

A texture analysis was then conducted on the dry pet food of Example 1. In general, the texture analysis measured and characterized the texture by the penetration depth of a probe with respect to the breaking point of the dry pet food matrix. (Specification, page 8, Example 2.)

The texture analysis of the dry pet food of Example 1 was compared to that of commercially available pet food products. The results indicated that the dry pet food of Example 1 was significantly more resistant to breakage than the standard and commercially available dry pet foods. With greater breakage resistance, the animal can bite deeper into each piece of the product before it breaks. In this regard, the animal's teeth are subjected to improved mechanical cleaning. (Specification, page 8, Example 2.)

Further, Appellants demonstrated how the dry pet food of the present invention can be utilized to effectively reduce plaque build up on pets' teeth. This was done by feeding the dry pet food product of the present invention to a number of cats in addition to feeding commercially available pet food products to a number of other cats. The level of plaque on each of the cat's teeth was analyzed and evaluated over a certain period of time. The test result clearly indicated that the dry pet food product of Example 1 showed significantly improved cleaning of the cats' teeth as compared to the commercially available dry pet foods. (Specification, pages 8-10, Example 3.)

## VI. ISSUES

The issues on Appeal are as follows:

1. Is the claim term "at least 2%" as defined by Claims 1, 13, 20 and 24 described in the Specification in such a way as to reasonably convey to one skilled in the art that the

inventor, at the time that the application was filed, had possession of the claimed invention pursuant to 35 U.S.C. § 112, first paragraph?

2. Are the dry pet food and method of reducing calculus and plaque build up on a pet's teeth as defined by Claims 1-3, 6-7, 13-15 and 18-24 anticipated by *Gellman* under 35 U.S.C. § 102(b)?

3. Are the dry pet food and method of reducing calculus and plaque build up on a pet's teeth as defined by Claims 1-20 and 24 anticipated by *Simone* under 35 U.S.C. § 102(b)?

## VII. GROUPING OF THE CLAIMS

Appellants argue for the separate patentability of each of the independent claims separate and apart from each other set forth in detail below pursuant to the requirements of 37 C.F.R. § 1.192(7), unless otherwise specified.

## VIII. ARGUMENT

### A. The Claimed Invention -- Independent Claims

On Appeal, there are five independent claims, namely, Claims 1, 8, 13, 20 and 24. Independent Claims 1, 8, 13, 20 and 24 provide as follows:

Independent Claim 1 recites a dry pet food comprising a matrix comprising a denatured protein source, a gelatinized carbohydrate source, at least 2% by weight insoluble fiber and a humectant in an amount sufficient for reducing brittleness of the matrix wherein the dry pet food has a moisture content of less than 10% by weight.

Independent Claim 8 recites a dry pet food comprising a matrix comprising a gelatinized protein source, a gelatinized carbohydrate source, about 2% to about 15% by weight of insoluble

fiber, about 0.5% to about 5% by weight of a humectant for reducing brittleness of the matrix wherein the dry pet food has a moisture content of less than 10% by weight.

Independent Claim 13 recites a dry cat food kibble comprising a matrix comprising a gelatinized protein source, a gelatinized carbohydrate source, at least 2% by weight insoluble fiber, and a humectant in an amount sufficient for reducing brittleness of the matrix wherein the kibble has a moisture content of less than 10% by weight and a length of at least 6 mm, a thickness of at least 6 mm, and in which the minimum distance from a center of gravity of the matrix to a surface of the matrix is about 3 mm.

Independent Claim 20 recites a method of reducing calculus and plaque build up on a cat's teeth. The method comprises administering to the pet a dry pet food comprising a gelatinized matrix including a protein source, a carbohydrate source, at least 2% by weight insoluble fiber and a humectant wherein the pet food has a moisture content of less than 10% by weight and reduced brittleness.

Independent Claim 24 recites a method of reducing calculus and plaque build up on a cat's teeth. The method comprises administering to the cat a dry kibble which contains at least 2% by weight of an insoluble fiber and a humectant, has reduced brittleness, a moisture content of less than 10% by weight, has a length of at least about 6 mm, a thickness of at least about 6 mm, and in which the minimum distance from a center of gravity of the matrix to a surface of the matrix is about 3 mm.

#### B. The Rejection

Claims 1, 13, 20 and 24 have been rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application

was filed, had possession of the claimed invention. The Patent Office essentially asserts that the amendment to the claims which requires “at least 2% by weight of insoluble fiber” introduces new matter into the claims.

Claims 1-3, 6-7, 13-15 and 18-24 have been rejected under 35 U.S.C. § 102(b) as being anticipated by *Gellman*. The Patent Office essentially asserts that *Gellman* teaches each and every feature of the claimed invention.

Claims 1-20 and 24 have been rejected under 35 U.S.C. § 102(b) as being anticipated by *Simone*. The Patent Office essentially asserts that *Simone* teaches each and every feature of the claimed invention.

C. The Claim Term “at least 2%” Is Sufficiently Described In The Original Specification To Meet The Requirements of 35 U.S.C. § 112

Appellants respectfully submit that the rejection of Claims 1, 13, 20 and 24 under 35 U.S.C. § 112, first paragraph, should be reversed. Claims 1, 13, 20 and 24 comply with the requirement of 35 U.S.C. § 112, first paragraph. The claim term “at least 2% by weight of insoluble fiber” as required by Claims 1, 13, 20 and 24 is clearly supported by the original Specification in such a way as to reasonably convey to one skilled in the relevant art that Appellants, at the time the application was filed, had possession of the claimed invention. Moreover, the Patent Office’s apparent reasoning as to why the claim term introduced new matter into the claims is misplaced. Therefore, Appellants respectfully submit that this rejection is incorrect as a matter of law and fact.

1. The Applicable Law

With respect to 35 U.S.C. §112, first paragraph, particularly the written description requirement, the Patent Office has the burden of “presenting evidence or reasons why persons

skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *Wertheim*, 541 F.2d at 263, 191 U.S.P.Q. at 97. The Court of Appeals for the Federal Circuit has further held that:

If, on the other hand, the specification contains a description of the claimed invention, albeit not *in ipsis verbis* (in the identical words), then the examiner or Board, in order to meet the burden of proof, must provide reasons why one of ordinary skill in the art would not consider the description sufficient.

*In re Alton*, 37 U.S.P.Q. 2d 1578, 1583 (Fed. Cir. 1996).

The essential inquiry in determining compliance with the "written description" requirement of 35 U.S.C. § 112, ¶ 1, is whether one skilled in the art, reading the specification, would identify the subject matter of the new claims as being invented and disclosed by the patentees. *Hester Industries, Inc. v. Stein Inc.*, 46 U.S.P.Q. 2d 1641, 1651 (Fed. Cir. 1998); and *In re Amos*, 21 U.S.P.Q. 2d 1271, 1274-75 (Fed. Cir. 1991). The function of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. *In re Edwards*, 196 U.S.P.Q. 465, 467 (CCPA 1998).

To comply with the written description requirement, it is not necessary that the application describe the claimed invention in *ipsis verbis*. *Id.* Indeed, it is immaterial how the application achieves compliance with the written description requirements. *In re Voss*, 194 U.S.P.Q. 267, 271 (CCPA 1977). Rather, the Court of Appeals for the Federal Circuit has held that:

If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the Specification, then the adequate written description requirement is met.

*In re Alton*, 37 U.S.P.Q. 2d at 1584 (Fed. Cir. 1996).

2. The Rejection of Claims 1, 13, 20 and 24 Under 35 U.S.C. § 112 Should Be Reversed Because The Claim Term “at least 2% by weight of insoluble fiber” is Sufficiently Described in the Specification as Originally Filed

Appellants respectfully submit that the rejection of Claims 1, 13, 20 and 24 under 35 U.S.C. § 112, first paragraph is improper as a matter of law and fact and therefore should be reversed. The claim term “at least 2% by weight of insoluble fiber” is clearly supported in the Specification as originally filed.

Independent Claims 1, 13, 20 and 24 each require, in part, “at least 2% by weight of insoluble fiber”. The Specification clearly supports this language. First, the Specification supports the limitation that the dried pet food of Claims 1, 13, 20 and 24 can include about 2% by weight of insoluble fiber. For example, the Specification discloses that “[t]he pet food preferably contains about 2% to about 15% by weight of insoluble fiber” on page 3 at lines 9-10. Further, the Specification discloses that “the dried pet food conveniently contains about 2% to about 15% by weight of insoluble fiber” on page 4 at lines 31-32. Indeed, the terms “preferably” and “conveniently” clearly indicate that the figure of “15%” should not be construed as an upper limit for the content of insoluble fiber.

It appears that the Examiner is not objecting to the limitation “at least 2%”, but the fact that there is no upper limit as to the amount of insoluble fiber. See, Advisory Action appended hereto as Exhibit D of the Supplemental Appendix. If this is the case, such a rejection is clearly improper. The Specification clearly supports that the dried pet food of Claims 1, 13, 20 and 24 can include greater than 2% by weight of insoluble fiber. This feature is clearly supported in the Specification, for example, on page 2 at lines 31-34 as follows:

in one aspect, this invention provides a dried pet food comprising a matrix including a denatured protein source, a gelatinized carbohydrate source; **insoluble fiber**; and a humectant in an amount sufficient for reducing brittleness of the matrix. (Emphasis Added).

Moreover, as originally filed, independent Claims 1, 13 and 20 required a dried pet food that included a matrix having an insoluble fiber with no upper limit. Thus, the claims as filed supported the use of any amount of insoluble fiber.

Appellants respectfully submit that the rejection is clearly not proper. Of course, it is axiomatic that:

*[I]psis verbis* disclosure is not necessary to satisfy the written description requirement under of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question.

*Fujikawa v. Wattanasin*, 39 U.S.P.Q. 2d 1895, 1904 (Fed. Cir. 1996). The Specification as filed disclosed to one skilled in the art and conveyed to the public that Appellants had possession of an invention including “at least 2% by weight of insoluble fiber”.

Accordingly, Appellants respectfully request that the rejection of Claims 1, 13, 20 and 24 under 35 U.S.C. § 112 be reversed.

D. None of the Cited References Anticipate Any of the Claims

Appellants respectfully submit that the rejection of Claims 1-24 under 35 U.S.C. § 102 should be reversed because the cited references fail to anticipate any of the pending claims. The alleged anticipating references relied on by the Patent Office each fail to teach each and every feature of the claimed invention of Claims 1-24.

1. Applicable Law

“Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in the prior art ...” *Akzo NV v. U.S. International Trade Commission*, 1 U.S.P.Q. 2d 1241, 1245 (Fed. Cir. 1986). The Court of Appeals for the Federal Circuit has held that “a claim is anticipated only if each and every element as set forth in the claim is found,

either expressly or inherently described, in a *single* prior art reference.” *Verdegaal Bros v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1988) (*emphasis added*). The Court of Appeals for the Federal Circuit has further held that:

For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. *See In Re Spada*, 911 F.2d 705, 708, 15 U.S.P.Q. 2d 1655, 1657 (Fed. Cir. 1990) (“[T]he [prior art] reference must describe the applicant’s claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it.” (citations omitted)). Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there.

*Motorola, Inc. v. Interdigital Technology Corp.*, 43 U.S.P.Q. 2d 1481, 1490 (Fed. Cir. 1997).

2. The Rejection of Claims 1-24 Under 35 U.S.C. § 102 Should Be Reversed Because The Patent Office Has Failed To Establish A *Prima Facie* Case of Anticipation

Appellants respectfully submit that the Patent Office has failed to establish a *prima facie* of anticipation with respect to the rejection of Claims 1-24 under 35 U.S.C. § 102. The alleged anticipating references, namely *Gellman* and *Simone*, are clearly deficient with respect to each and every feature of the claimed invention. Therefore, Appellants respectfully submit that either of these references fails to teach the claimed invention as required by Claims 1-24.

A. The Dry Pet Food Features of the Claimed Invention

Claims 1-24 are pending on this Appeal. Each of independent Claim 1, 8 and 13 require a dry pet food that includes, in part, a matrix of a protein source, a gelatinized carbohydrate source, insoluble fiber, and a humectant in an amount sufficient for reducing brittleness of the matrix. These claims also recite that the protein source is denatured (Claim 1) or gelatinized (Claims 8 and 13). These independent claims further recite a moisture content of less than 10%

by weight (Claims 1, 8 and 13), at least 2% by weight of insoluble fiber (Claims 1 and 13) and about 2% to about 15% by weight of insoluble fiber (Claim 8).

Independent Claims 20 and 24 each recite a method of reducing calculus and plaque build up on a pet's teeth, such as a cat (Claim 24). Each of independent Claims 20 and 24 further recite administering to the pet a dry pet food that has features similar to those of the dry pet food as required by Claims 1, 8 and 13.

As previously discussed, Appellants have surprisingly discovered that the dry pet food of the claimed invention can significantly reduce the brittleness of pet food without compromising on the hardness that is needed to accomplish mechanical cleaning by abrasion. In doing so, the pet's teeth can penetrate into the pet food for a longer distance prior to the breaking of the pet food. In this regard, the pet's teeth can be in contact with the pet food for a longer period of time. This subjects the pet's teeth to the abrasive effect of the pet food for a longer time thus effectively reducing the calculus and plaque build up on the pet's teeth. Moreover, Appellants have demonstrated that the dry pet food of the claimed invention exhibits significantly improved cleaning of a pet's teeth, even as compared to commercially available dry pet foods as previously discussed.

2. Gellman and Simone Are Deficient With Respect To The Dry Pet Food Features Of The Claimed Invention

As previously discussed, Claims 1-24 have been rejected under 35 U.S.C. § 102. More specifically, Claims 1-3, 6-7, 13-15 and 18-24 have been rejected under 35 U.S.C. § 102 as being anticipated by *Gellman*; and Claims 1-20 and 24 are rejected under 35 U.S.C. § 102 as being anticipated by *Simone*.

At the outset, Appellants submit that the rejections of Claims 1-24 under 35 U.S.C. § 102 are improper based on the fact that the Patent Office has failed to establish a *prima facie* case of anticipation. Of course, "for a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art." *Motorola, Inc. v. Interdigital Technology Corp.*, 43 U.S.P.Q.2d at 1490 (Fed. Cir. 1997).

With respect to the anticipation rejection of Claims 1-3, 6-7, 13-15 and 18-24 in view of *Gellman*, the Patent Office mistakenly interprets this teaching to necessarily include an insoluble fiber source as required by Claims 1-3, 6-7, 13-15 and 18-24, let alone at least 2% by weight of an insoluble fiber source as required by the claimed invention. Although *Gellman et al.* discloses flour and other farinaceous material, clearly, *Gellman* is not concerned with whether or not the fiber that is provided is soluble or insoluble. In this regard, *Gellman* merely uses starchy substances to aid in the cost reduction of the product. *See*, Exhibit B, *Gellman*, column 10, lines 10-14.

*Gellman* also does not specifically teach that the starch or the protein or the matrix formed from the starch and the protein should be gelatinized. The relatively low pressure and low temperature processing conditions and steps taught by *Gellman* would also not be expected to produce the particular gelatinized product of this invention. This results from the choice of higher pressure and temperature extrusion conditions that obviate the need for post extrusion baking and which do not produce the "soft biscuit" repeatedly referred to by *Gellman*. *See*, *Gellman* for example, column 1, lines 15 and 19, col. 5, line 13, col. 3, line 47 and col. 8, line 30.

Based on the fact that *Gellman et al.* fails to teach or suggest a pet food product that includes an insoluble fiber source, let alone at least 2% by weight of an insoluble fiber source, Appellants submit that *Gellman* fails to anticipate Claims 1-3, 6-7, 13-15 and 18-24 under 35 U.S.C. § 102.

With respect to the rejection of Claims 1-20 and 24 under 35 U.S.C. § 102, the Patent Office essentially asserts that *Simone* teaches a dried pet food product, particularly one that includes a moisture content of about 10% by weight. Appellants respectfully submit that this is not a fair reading of *Simone*.

At the outset, *Simone* fails to teach a dried pet food as required by each of the independent claims. Contrary to the Patent Office's interpretation, the clear emphasis of *Simone* is on chew products and not food products. *See*, Exhibit A, page 3-4.

Indeed, *Simone* discloses that its chew products were fed to dogs to supplement a normal can diet. *See*, Exhibit C, *Simone*, column 8, lines 26-30. Canned pet foods have high moisture content, usually about 55%-70%, and are therefore wet and necessarily soft, providing negligible abrasive cleaning effect. Most pets tend to gulp them down with minimal chewing. Hence the need identified by *Simone* to provide something chewy, separately from the meal. *Simone* did not imagine or address providing a hard and chewable pet food with tooth cleaning properties. Thus, one cannot compare a product, such as *Simone*, to the dried pet food product of the claimed invention which is intended for feeding a meal to the pet and at the same time encouraging longer chewing. In *Simone*, the pet, at best, chews on the product while getting hungrier as it chews.

Regardless, in contrast to *Simone*, independent Claims 1, 8, 13, 20 and 24 each require a dried pet food that includes, in part, a moisture content of less than 10% by weight. *Simone* fails to disclose a moisture level below 10% by weight. Indeed, *Simone* specifically claims that

the moisture level is equal to or greater than 12% by weight. *See, Exhibit C, Simone, Claims 1 and 17.* As defined in the Specification in column 5 at lines 5-10, *Simone* discloses that the moisture level is preferably 16% to 35% by weight. *See, Exhibit C.*

Although *Simone* discloses that the expanded cellular product as it leaves the extruder has a moisture content of about 10% to about 35% (*See, Exhibit C, Simone et al., column 7, lines 17-21*), this teaching applies to an intermediary product and not a final product as incorrectly asserted by the Patent Office. *Simone* further discloses that the expanded and extruded cellular product is "subdivided into longitudinal one to five inch sections and allowed to cool and dry to a moisture content of about 12% to about 35% by weight water" and not less than 10%. *See, Exhibit C, Simone, column 7, lines 22-28.*

Of course, "the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public." *Akzo N.V. v. U.S. International Trade Commission*, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In this regard, *Simone* is clearly not enabling with respect to a moisture content of less than 10% by weight as required by the claimed invention.

Indeed, what *Simone* clearly emphasizes is a moisture content of 12% or more. *See, Exhibit C, Simone, column 5, lines 5-10, Claims 1 and 17.* Contrary to the Patent Office's assertion (*See, Exhibit D, Advisory Action*), *Simone*'s sole reference to a moisture level of about 10% to about 30% by weight, if anything, indicates a moisture level of 10% or more and not less than 10% as required by the claimed invention.

Based on the fact that *Simone* fails to teach each and every feature, such as the dried pet food and moisture content features, of independent Claims 1, 8, 13, 20 and 24, Appellants submit that *Simone* fails to anticipate independent Claims 1-20 and 24.

Appellants note for the record that the Patent Office did not explicitly address whether the previous rejection of Claim 24 under 35 U.S.C. § 103 in view of U.S. Patent No. 5,431,927 (“*Hand*”) had been withdrawn. The Patent Office raised this rejection in the Office Action mailed on August 15, 2000 appended hereto as Exhibit E of the Supplemental Appendix.

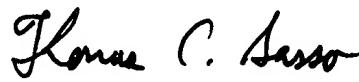
To the extent that this rejection still applies, Appellants submit that it is improper and should be reversed. Clearly, *Hand* does not disclose or suggest the use of a humectant. In contrast, Claim 24 was previously amended to specifically include a humectant in the kibble used in the claimed method.

Accordingly, Appellants respectfully request that the rejection of Claims 1-24 under 35 U.S.C. § 102 should be reversed.

#### IX. CONCLUSION

Appellants respectfully submit that the rejection of Claims 1, 13, 20 and 24 under 35 U.S.C. § 112 is erroneous in law and fact and should therefore be reversed by this Board. Moreover, Appellants respectfully submit that the rejection of Claims 1-24 under 35 U.S.C. § 102 is erroneous in law and fact and should also be reversed.

Respectfully submitted,



(46,541)

Thomas C. Basso, Esq.  
BELL, BOYD & LLOYD LLC  
P.O. Box 1135  
Chicago, Illinois 60690-1135  
Telephone: (312) 807-4310  
ATTORNEYS FOR APPELLANTS

381175v1/D

## APPENDIX

1. A dried pet food comprising a matrix comprising a denatured protein source, a gelatinized carbohydrate source, at least 2% by weight insoluble fiber, a humectant in an amount sufficient for reducing brittleness of the matrix; and the dried pet food having a moisture content of less than 10% by weight.
2. A dried pet food according to claim 1 which comprises about 0.5% to about 5% by weight of a humectant.
3. A dried pet food according to claim 2 in which the humectant is glycerin.
4. A dried pet food according to claim 1 which comprises about 2% to about 15% by weight of insoluble fiber.
5. A dried pet food according to claim 4 in which the insoluble fiber is a cellulose fiber.
6. A dried pet food according to claim 1 which has a density of about 250 kg/m<sup>3</sup> to about 320 kg/m<sup>3</sup>.
7. A dried pet food according to claim 1 in the form of a cat kibble which has a length of at least 6 mm, a thickness of at least 6 mm, and in which the minimum distance from a center of gravity of the matrix to a surface of the matrix is about 3 mm.
8. A dried pet food comprising a matrix comprising a gelatinized protein source, a gelatinized carbohydrate source, about 2% to about 15% by weight of insoluble fiber, about 0.5%

to about 5% by weight of a humectant for reducing brittleness of the matrix; and the dried pet food having a moisture content of less than 10% by weight.

9. A dried pet food according to claim 8 in which the humectant is glycerin.

10. A dried pet food according to claim 8 in which the insoluble fiber is a cellulose fiber.

11. A dried pet food according to claim 8 which has a density of about 250 kg/m<sup>3</sup> to about 320 kg/m<sup>3</sup>.

12. A dried pet food according to claim 8 in the form of a cat kibble which has a length of at least 6 mm, a thickness of at least 6 mm, and in which the minimum distance from a center of gravity of the matrix to a surface of the matrix is about 3 mm.

13. A dried cat food kibble comprising a matrix comprising a gelatinized protein source, a gelatinized carbohydrate source, at least 2% by weight insoluble fiber, and a humectant in an amount sufficient for reducing brittleness of the matrix, the kibble having a moisture content of less than 10% by weight and a length of at least 6 mm, a thickness of at least 6 mm, and in which the minimum distance from a center of gravity of the matrix to a surface of the matrix is about 3 mm.

14. A dried cat food kibble according to claim 13 which comprises about 0.5% to about 5% by weight of a humectant.

15. A dried cat food kibble according to claim 13 in which the humectant is glycerin.
16. A dried cat food according to claim 13 which comprises about 2% to about 15% by weight of insoluble fiber.
17. A dried cat food kibble according to claim 13 in which the insoluble fiber is a cellulose fiber.
18. A dried cat food kibble according to claim 13 which has a density of about 250 kg/m<sup>3</sup> to about 320 kg/m<sup>3</sup>.
19. A dried cat food kibble according to claim 13 into which a probe, having a contact area of about 1 mm<sup>2</sup> and operated at a speed of about 5 mm/s, penetrates into the matrix for a distance of at least 30% of the thickness of the matrix prior to breaking of the matrix.
20. A method of reducing calculus and plaque build up on a pet's teeth, the method comprising administering to the pet a dried pet food comprising a gelatinized matrix including a protein source, a carbohydrate source, at least 2% by weight insoluble fiber, and a humectant, the pet food having a moisture content of less than 10% by weight and reduced brittleness.
21. A dried pet food according to claim 1 which has a moisture content of about 3% to about 7% by weight.
22. A dried kibble according to claim 8 which has a moisture content of about 3% to about 7% by weight.

23. A dried cat food kibble according to claim 13 which has a moisture content of about 3% to about 7% by weight.

24. A method of reducing calculus and plaque build up on a cat's teeth, the method comprising administering to the pet a dried kibble which contains at least 2% by weight of insoluble fiber and a humectant, has reduced brittleness, a moisture content of less than 10% by weight, and has a length of at least about 6 mm, a thickness of at least about 6 mm, and in which the minimum distance from a center of gravity of the matrix to a surface of the matrix is about 3 mm.

Exhibit A



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/154,646	09/17/98	CUFF	P97-2391
		IM62/0102	<input type="checkbox"/> EXAMINER
BELL, BOYD & LLOYD, LLC P. O. BOX 1135 CHICAGO IL 60690-1135			HENDRICKS, K
			<input type="checkbox"/> ART UNIT <input type="checkbox"/> PAPER NUMBER

1761

DATE MAILED:

01/02/01

REPLY DUE:  
4/2/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

RECEIVED  
MAY 25 2001  
TC 1700

RECEIVED  
BELL, BOYD & LLOYD  
INTELLECTUAL PROPERTY DOCKET

JAN - 4 2001 *BB*  
ATTY: RuB  
DOCKET #: 112701-021

## Office Action Summary

Application No.	Applicant(s)	
60/184,666		
Examiner	Group Art Unit	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 10/22/00 *REPLY DUE*  
 This action is FINAL. 4/21/2001  
 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1 - 24 is/are pending in the application.  
Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 1 - 20 & 24 is/are rejected.  
 Claim(s) 21 - 23 is/are objected to.  
 Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413 *RECD*  
 Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152 *RECD*  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

RECEIVED  
MAY 25 2001  
TC 1700

## Office Action Summary

Art Unit: 1761

**DETAILED ACTION*****Remarks***

In the previous Office action, it was noted that the references and impending rejections were discussed with applicants' representative on May 22, 2000, as well as suggestions for amending the claims, but did not result in an agreement at that time. Applicants' representative acknowledged the conference, stating that the examiner suggested limiting the claims to "at least 2% by weight" of the product being insoluble fiber, and amending claim 24 to include a humectant, the claims would be allowable over the prior art. To clarify the record, the conversation took place prior to the Office action (Paper #8, August 15, 2000), which provides several claim rejections. ~~Applicants must address each rejection as it appears in the previous Office action.~~ *Jack* *Humectant* Further, as noted below, "at least 2%" insoluble fiber is not supported by the specification, nor was this suggested anywhere in the Office action. Thus a possible misunderstanding may have occurred during the months between the conversation, the Office action, and the time following the Office action until response. It is noted that the specification and previous claims support language directed to ~~about 2% to about 15%~~ by weight of insoluble fiber", but not any amount above "at least 2%".

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1761

Claims 1,13,20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' amendment of October 20, 2000, introduces new matter to the claims, which is not supported by the teachings of the original specification. It is noted that the specification and previous claims support language directed to "~~about 2% to about 15% by weight~~ of insoluble fiber", but not any amount above "at least 2%". Correction and deletion of the new matter is required.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-7, 13-15 and 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gellman et al.

Applicants' arguments filed October 20, 2000 have been fully considered but they are not persuasive. At pages 2-3 of the response, applicants state that "Gellman does not disclose adding at least 2% by weight insoluble fiber to a pet food product." This is not deemed persuasive for the reasons of record, as namely, applicants' specification also does not disclose ~~adding at least 2% by weight insoluble fiber~~ to a pet food product, and thus the limitation cannot be properly maintained within the claim.

Art Unit: 1761

Applicants further state that "Gellman does not specifically teach the use of insoluble fiber." However, this point is not deemed persuasive, and had been addressed previously on the record (pg. 3, previous Office action). Specifically again,

Insoluble fiber is not specifically mentioned as an ingredient; however, the farinaceous materials described at column 10 naturally contain some amount of fiber. For example, wheat generally contains 2.3- 5.6% total dietary fiber, with 1.7% of that insoluble, including cellulose. Corn flour has 15% insoluble fiber, including cellulose. (pg. 481, 484. Lorenz et al. "Handbook of Cereal Science and Technology", Dekker Press, 1991). Although this does not reach the threshold of ~~"about 2% to about 15%"~~ instant claims 4-5,8-12,16-17), the instantly-rejected claims are anticipated by the reference.

Claims 1-20 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Simone et al.

Applicants' arguments filed October 20, 2000 have been fully considered but they are not persuasive. At page 3 of the response, applicants state that "Simone discloses that the moisture content of the product disclosed therein is preferably at least 12% by weight or greater", while each of applicants' claims "requires a moisture content of less than 10% by weight." Applicants also misquote the reference and Office action by stating that "a level of 10-30% by weight" would not read upon the instant claims. This is not deemed persuasive for the reasons of record. Initially, it is not agreed that Simone teaches that the moisture content must be "at least 12% by weight", or even "a level of 10-30% by weight". In fact, this point was specifically addressed at page 4 of the previous Office action.

Simone et al. teach that the moisture content of the final product can be dried "to adjust the moisture level to about 10 to about 30% by weight" (bottom of column 5, col. 7, lines 19 and 27 as "dried" thereafter).

As the teaching of "about 10" percent moisture by weight includes percentages immediately above and below 10%, and at the very least, below 12% as purported by applicant, the claimed invention

*is at 10% & not 10%*

Art Unit: 1761

is anticipated by the reference. The preferred percentages of the exemplified product of Simone et al. do not detract from the broader recitation specifically recited within the same reference, which provides a functional product which overlaps with the instantly-claimed invention.

***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gabrielle Brouillette, can be reached at (703) 308-0756. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



KEITH HENDRICKS  
PRIMARY EXAMINER

Exhibit B

# United States Patent [19]

Gellman et al.

[11] Patent Number: 4,743,460

[45] Date of Patent: May 10, 1988

[54] SOFT CANINE BISCUIT CONTAINING DISCRETE PARTICLES OF MEAT AND OTHER MATERIALS AND METHOD FOR MAKING SAME

[75] Inventors: Gary Gellman, Summit; George A. Erfurt, Lawrenceville; James E. Roe, Wayne, all of N.J.

[73] Assignee: Nabisco Brands, Inc., Parsippany, N.J.

[21] Appl. No.: 736,247

[22] Filed: May 21, 1985

## Related U.S. Application Data

[63] Continuation of Ser. No. 549,353, Nov. 7, 1983, Pat. No. 4,534,990, which is a continuation-in-part of Ser. No. 341,970, Jan. 22, 1982, Pat. No. 4,454,164.

[51] Int. Cl. 4 A23K 1/00

[52] U.S. Cl. 426/549; 426/623; 426/630; 426/646; 426/805

[58] Field of Search 426/92, 94, 549, 555, 426/560, 623, 630, 512, 646, 466, 805; 119/29.5

## References Cited

### U.S. PATENT DOCUMENTS

113,063	3/1871	Kirkwood	.
248,247	11/1881	Witsil	426/641
309,502	12/1884	Wylam	.
309,503	12/1884	Wylam	.
982,711	1/1911	Ellis	119/29.5
1,018,415	3/1912	Ellis	.
2,138,177	11/1938	Kruger et al.	.
2,878,127	3/1959	Forkner	426/94
3,134,677	5/1964	Glae	426/94
3,656,966	4/1972	Ball	426/94
3,808,340	4/1974	Palmer	426/805
3,808,341	4/1974	Rongey	426/305
3,883,672	5/1975	Bone et al.	426/311
3,976,799	8/1976	Kelly et al.	.
4,032,665	6/1977	Miller et al.	426/104
4,039,689	8/1977	Bone	426/99
4,055,681	10/1977	Balaz et al.	426/656
4,145,447	3/1979	Fisher et al.	426/72
4,229,485	10/1980	Brown et al.	426/305

## FOREIGN PATENT DOCUMENTS

1310348	3/1973	United Kingdom	426/641
1465055	2/1977	United Kingdom	.
1465267	2/1977	United Kingdom	.

## OTHER PUBLICATIONS

Barnhart, "The American College Dictionary", Random House Publishers, (1970), p. 146.

Lustig et al., The Southern Cook Book of Fine Old Receipts, Culinary Arts Press, Reading, Pa., (1950), pp. 30-31.

Websters, Third New International Dictionary, Merriam Co. Publishers, (1961), p. 528.

Matz, Samuel A., "Cereal Technology", (1970), pp. 105 to 107.

Chemical Engineers' Handbook, Perry, Editor, 4th Ed., (1963), pp. 8-63 and 8-64.

Primary Examiner—R. B. Penland

Attorney, Agent, or Firm—Richard Kornutik

[57]

## ABSTRACT

A dry soft canine biscuit having visually apparent, discrete particles, which contain (i) meat and/or meat by-product and/or (ii) farinaceous material and/or textured vegetable protein, distributed substantially uniformly throughout the biscuit is obtained by blending the non-fat solid portion of a soft biscuit dough with particles which are substantially inert with respect to the biscuit dough, mixing the dry-blended mixture with water plus optional humectant to form an intermediate stage dough, admixing the latter with the fat portion of the biscuit dough to form a final dough, forming the final dough using low shear into pieces, and baking and drying the formed pieces to obtain a microbiologically stable product which can be packaged without a barrier material. The particle inertness is made possible by using particles having: (1) a moisture content of 35 percent by weight or less and, (2) a water activity which is less than the water activity of the soft biscuit dough. There is a substantial absence of particle color bleed into the biscuit. An example of the textured vegetable protein is textured soy protein; and an example of the farinaceous material is wheat. The discrete, visually apparent dehydrated meat particles enhance the palatability and visual attractiveness of the dry biscuit.

18 Claims, No Drawings

**SOFT CANINE BISCUIT CONTAINING DISCRETE PARTICLES OF MEAT AND OTHER MATERIALS AND METHOD FOR MAKING SAME**

This is a continuation of application Ser. No. 549,353, filed on Nov. 7, 1983, now U.S. Pat. No. 4,534,990, which is a continuation-in-part of application Ser. No. 341,970, filed on Jan. 22, 1982, now U.S. Pat. No. 4,454,164.

**BACKGROUND OF THE INVENTION**

**1. Field of the Invention**

The invention relates to a method for incorporating animal protein into a biscuit dough to obtain a dry soft canine biscuit having animal protein particles which are visually apparent as discrete particles and which are distributed substantially uniformly throughout the biscuit. The invention also relates to a dry soft canine biscuit containing discrete animal protein particles. The invention products have enhanced palatability and enhanced eye appeal. The invention further relates to a method of preparing such particles.

**2. Description of the Prior Art**

Dry pet food are commonly cereal type materials having a low moisture content of less than about 15 percent by weight. As a result of their low moisture content, they resist mold growth and bacterial spoilage. Additionally, they can often be packaged and stored in containers, such as a box, without the need for hermetic sealing and without the need for a moisture barrier. Dry pet foods typically have low palatability because of their low moisture content.

The incorporation of meat products, fish products, and poultry products into a farinaceous pet food to improve palatability and to improve nutritional values of dry pet foods, intermediate moisture products and high moisture content pet foods (more than about 50 percent by weight of water) is known in the art.

U.S. Pat. No. 3,946,123 discloses an aqueous suspension or broth of meat and meat by-products consisting in part or entirely of fish and flavored cereal chunks. The meat and meat by-products that may be used include those of fowl and fish as well as that of mammals such as cattle, swine, goats and the like. Due to the high moisture content of the product, it must be packaged in cans. In U.S. Pat. No. 4,158,706 a high moisture pet food product containing farinaceous and proteinaceous components such as meats, fish and poultry is impregnated with a preservative such as succinic acid to enable packaging within a paper or polymer film. These high moisture content products have a high shipping weight for a given amount of nutritive value and do not provide a hard surface for the strengthening of gums and for the removal of plaque from teeth.

The production of dry pet foods which contain proteinaceous and farinaceous material is disclosed in U.S. Pat. Nos. 3,962,462, 4,020,187, 4,039,689, 4,055,681, 4,145,447, 4,215,149 and 4,229,485.

In U.S. Pat. No. 3,962,462 the ingredients are first dry-blended and then water and water-containing ingredients are added until a cohesive dough is formed. A stabilizing system comprising a sugar, an edible acid and an antimycotic provides stability within the pet food when the pet food is subjected to semi-moist conditions. The product is produced in wafer form for packaging with a semi-moist pet food. The proteinaceous material includes meat, such as the flesh of cattle, swine, sheep,

poultry and fish, as well as various meals such as meat and bone meal, fish meal and the like.

In U.S. Pat. No. 4,020,187 tallow or lard is added to a water slurry of a ground mixture of meat and meat by-products to raise the resulting fat content of the mixture to at least 25 percent. The resulting mixture is then homogenized to liquefy and reduce the particle size and to uniformly distribute the fat content through the meat mixture. Dry farinaceous ingredients are ground and added to the homogenized meat mixture. The blended mixture is subjected to temperatures of from 225° to 325° F. at a pressure of at least about 50 p.s.i. The product is expanded, cut and dried to obtain a product having a final moisture content of from 7 to 15 percent. The product, it is disclosed, is not externally greasy and may be packaged in ordinary paper bags or in plastic wrap.

A dry, but soft, pet food is produced in U.S. Pat. No. 4,039,689 using low temperatures and pressures. The use of the low processing temperatures, less than about 130° F., leads to the soft dry nature of the pet food, it is disclosed. Meat and meat by-products as well as dried animal by-products can be used as a protein source for the pet food in U.S. Pat. No. 4,039,689. The dried animal by-products include meat meal and bone meal.

U.S. Pat. No. 4,055,681, like U.S. Pat. No. 4,039,689, produces a soft dry pet food having a meat-like texture and appearance. Meat meal is disclosed as a protein source and fresh meat and meat by-products are used to impart palatability to the pet food.

In the production of the dry pet food products according to the processes of the above patents, the use of wet meat products causes substantial smearing or blending of the meat into the farinaceous material. It also causes bleeding of the protein colors into the farinaceous material which reduces the visual attractiveness of the product to the consumer and which reduces the product's hardness.

A hard dry pet food is produced in U.S. Pat. No. 4,145,447. High pressures of at least about 100 p.s.i. are used to obtain a product which is hard enough to provide chew-resistance for the removal of plaque or tartar from the animal's teeth. The product is a long-lasting one which requires about 30 minutes to 2 hours for a 25 lb. dog to consume. Dry components are mixed until homogeneous and then sufficient water is added to wet the product without affecting the apparent dry, free-flowing characteristic of the product. The wetted product is then compacted at a pressure of at least 100 p.s.i., followed by heating or baking the compacted product at a temperature of at least about 200° F. The product can contain air-dried, freeze-dried or irradiated foods such as meat, fish, fish meal, cereals, fruits, vegetables and the like. Protein fibers, such as those derived from soy protein and wheat gluten, or animal fibers, such as those derived from skin, muscles, and intestines, are optionally added to support the structure of the product. The animal fibers can be prepared by cutting, chipping, grinding, shredding, shearing or beating animal skins such as cowhide or rawhide. The high pressure used in the process of U.S. Pat. No. 4,145,447 makes the process costly. Also, the structure-supporting fibers derived from animal tissue, which are optionally used in the process of U.S. Pat. No. 4,145,447, are low in palatability. Furthermore, a product having discrete, visually apparent, meat particles is not disclosed.

U.S. Pat. Nos. 4,215,149 and 4,229,485 disclose processes for improving the palatability of dry pet foods by

applying a coating, which contains proteins derived from animals, to the surface of the pet food. In U.S. Pat. No. 4,215,149 the surface of the pet food is treated with fat and then with a phosphoric acid salt. Treatment of the surface of the pet food with meat flavors and animal proteins is optional. Heating of the coated pet food, it is disclosed, must be avoided.

In U.S. Pat. No. 4,229,485 a dry biscuit is coated with a continuous glazed liver coating and is then baked to less than 18 percent moisture by weight. The liver preferably constitutes at least about 50 percent by weight of the coating, exclusive of moisture. The liver coating contains farinaceous material and comminuted liver. The hard glazed coating, it is disclosed, has the visual appearance of a meat coating to enhance the product's attractiveness to pets. The dry biscuits to which the liver coating is applied are obtained by baking a combination of uncooked farinaceous material and uncooked meat or meat by-products. The use of the uncooked meat or meat by-products in the form of finely cut flakes, preferably having their largest dimension in the range of 0.015 inch to 0.250 inch, it is disclosed, is necessary for obtaining high palatability of the product. However, the use of uncooked meat or meat by-products results in the blending of the protein color into the farinaceous material. Additionally, the flakes present in the biscuit are not visually apparent because of the liver coating.

U.S. Pat. No. 4,310,558 teaches producing a dry pet food product containing fibrous food pieces having a tough, pliable texture combined with a basal matrix containing proteinaceous and farinaceous materials having a porous texture and appearance. The fibrous food pieces, which may simulate vegetables, grains and red meat pieces, comprise denatured proteinaceous material. The food pieces are blended with undenatured proteinaceous materials and farinaceous materials. The mixture is mechanically worked under conditions of elevated temperature and pressure and finally extruded to form an expanded dry pet food product having a porous texture interspersed with food pieces having a tough, pliable fibrous texture. The mechanical working and forming is basically done in a cooker extruder, which utilizes high shear and substantial pressure.

#### BROAD DESCRIPTION OF THE INVENTION

An object of the invention is to provide dry, soft canine biscuits, which contain meat and/or meat by-product plus farinaceous material and/or textured vegetable protein, distributed substantially uniformly throughout the biscuits. Another object of the invention is to provide a method for making such dry, soft canine biscuits. A further object of the invention is to provide dry, soft canine biscuits and method of producing such biscuits which overcome the disadvantages of the above prior art. A still further object is to provide a process for making such particles. Other objects and advantages of the prior art are set out herein or obvious herefrom to one ordinarily skilled in the art.

The objects and advantages of the invention are achieved by the dry, soft canine biscuit and the production method of the invention.

According to the invention, there is provided a dry, soft canine biscuit having discrete particles, which contain meat and/or meat by-product and which can also contain farinaceous material and/or textured vegetable protein, distributed substantially uniformly throughout the biscuit. The particles are visually apparent as dis-

crete particles, do not separate from the remaining, or farinaceous portion of the biscuit during shipping, and enhance the palatability of the biscuit by providing a flavor impact. The product is highly stable and can be packaged directly into a paper board box. The method for making the dry, soft canine biscuit of the invention is economical, does not involve the use of high pressures and/or high shear to compact the biscuit dough as in U.S. Pat. Nos. 4,145,447 or 4,229,485 avoids substantial bleeding of the animal protein color into the farinaceous material, maintains particle discreteness and achieves substantially uniform distribution of the particles throughout the biscuit. Even with the inclusion of farinaceous material and/or textured vegetable protein in the particles, there is not any loss of discreteness of the particles in the final dry, soft canine biscuit. Suitable food-pet food grade dyes are used in the formation of the particles in order to color dark brown the farinaceous material and/or textured vegetable protein in the particles. Such dye does not run, bleed or the like when the particles are incorporated into the final biscuit.

The invention includes a method for making a dry, soft canine biscuit having enhanced palatability and enhanced eye appeal. Discrete particles, which contain meat and/or meat by-product and which can also contain farinaceous material and/or textured vegetable protein are distributed substantially uniformly throughout the dry, soft canine biscuit and are visually apparent to the consumer as discrete particles. The presence of meat-containing particles substantially above or on the biscuit surface is kept to minimum to reduce the opportunity for meat particle loss from physical abuse during transit. This particle distribution is accomplished by first dry-blending the meat particles with the non-fat solids portion of a biscuit dough, admixing the dry-blended mixture with water plus optional humectant and then adding the fat portion of the biscuit dough to form a dough. The invention process forms the dough using low pressure and/or low shear, preferably as little pressure and/or shear as possible, forming means or techniques. Alternatively, the water and fat can be admixed simultaneously with the dry-blended mixture. Meat and/or meat by-product containing particle visual awareness and biscuit hardness maintenance are achieved by using particles which are inert with respect to the biscuit dough. Meat and/or meat by-product containing particle inertness is made possible through the use of particles: (a) having a moisture content of 35 percent by weight or less; and (b) having a water activity which is less than the water activity of the biscuit dough during mixing, if the biscuit dough ingredients were mixed without particles containing the meat and/or meat by-product.

The invention also includes a process for preparing the particles which contain meat and/or meat by-product plus farinaceous material and/or textured vegetable protein. The inclusion of the non-meat material in the particles provides a significant cost reduction as compared to all meat and/or meat by-product particles. Particles of meat and/or meat by-product plus farinaceous material and/or textured vegetable protein which are stable, cohesive and have particle integrity as such or in a biscuit, are unexpected to the art.

The process for preparing the dry, cohesive particles which contain meat and/or meat by-product plus farinaceous material and/or textured vegetable protein, for use in dry, soft canine biscuits includes admixing the meat in particulate form and/or meat by-product in

particulate form with the farinaceous material in particulate form and/or the vegetable protein in particulate form. The admixture is formed by mechanically working the mass at conditions of elevated temperatures above about 212° F. and pressure for a time sufficient to convert the mass into a flowable substance and extruding the flowable substance through a restricted orifice. The extruder is particulated and the particles are dried to form dry, cohesive particles.

#### DETAILED DESCRIPTION OF THE INVENTION

The dry soft canine biscuit of the invention comprises discrete, visually-apparent particles, which contain meat and/or meat by-product and which can also contain farinaceous material and/or textured vegetable protein, which are uniformly distributed throughout the biscuit. The remaining, or non-meat by-product particle portion of the biscuit is substantially free of meat particles color. The biscuits are very stable microbiologically, and can be stored without refrigeration and without a packaging barrier material such as plastic film. The biscuit can be in various shapes such as square, round, triangular tubular, cylindrical, rectangular and the like. The preferred shapes are tubular, cylindrical. The tubular shape can contain a co-extruded farinaceous filler. The biscuits can be a thickness typical of canine biscuits. A preferred thickness is about  $\frac{1}{2}$  inch.

The particles containing meat and/or meat by-product used in the invention can be in the form of specs, flakes, chunks, chips, granules and the like. Herein, unless otherwise noted, the phrase "particles containing meat and/or meat by-product" or its equivalent wording is meant to include the partial substitution by the farinaceous material and/or textured vegetable protein for the meat and/or meat by-product in the particles. The particles should be of sufficient size as to be visually apparent to the consumer as discrete particles when in the biscuit of the invention. Prior to incorporation into the biscuit, the particles containing meat and/or meat by-product should preferably have a diameter or granulation of between about 1/32 of an inch and  $\frac{1}{2}$  inch. The final biscuit will also have particles approximately in this size range. Mixtures of particles within this size range or particles having a given size within this range can be used.

Particle visual awareness and biscuit hardness maintenance are achieved by using particles containing meat and/or meat by-product which are inert with respect to the biscuit. Meat and/or meat by-product containing particle "inertness" herein means (a) the particle does not smear into the biscuit dough and retains its integrity through production of the final product, (b) that the color of the particles containing meat and/or meat by-product particle does not substantially bleed into the biscuit dough (including any dye or colorant added to color dark brown the farinaceous material and/or textured vegetable protein in the particles), and (c) that ingredients, including any farinaceous material and/or textured vegetable protein substitutes, within the particles containing meat and/or meat by-product do not adversely affect the hardness and microbiological stability of the final biscuit product.

Meat and/or meat by-product containing particle inertness is made possible by using meat and/or meat by-product containing particles having: (1) a moisture content of about 35 percent by weight or less and, (2) a water activity which is less than the water activity of

the biscuit dough during mixing of the dough, if the biscuit dough ingredients were mixed without the meat or meat by-product containing particles. The lower water activity of the meat and/or meat by-product containing particles substantially prevents the flow of water and protein color from the particles to the dough during mixture of the dough ingredients and the particles. Higher moisture contents of the softer particles into the dough, thereby losing meat and/or meat by-product containing particle integrity. Also, higher moisture contents could create hardness reduction by the formation of steam pockets which turn into air voids upon biscuit leavening. The discreteness of the particles is locked in during drying of the dough.

Fresh meat and/or meat by-products can be dehydrated by known methods to achieve a moisture content of less than about 35 percent by weight. Dehydration also reduces the water activity of the meat and/or meat by-products. Generally, fresh beef has a moisture content of about 65 percent by weight and a water activity of about 1.0. Dehydrating the fresh meat to a moisture content of about 40 percent results in a water activity of about 0.8. Dehydration to about 12 to 20 percent by weight of water results in a water activity for the meat of about 0.7 and lower. Biscuit doughs generally have a water activity of about 0.90 and above completion of mixing of the non-fat solids portion, the water and the fat portion of the dough. Preferably, meat and/or meat by-products having a moisture content of less than or equal to about 20 percent by weight are used because they remain shelf stable without refrigeration prior to incorporation into the biscuit.

Microbiological stability of the meat and/or meat by-product containing particle ingredient is preferably achieved through a low water activity of 0.70 or less. This low water activity is preferably achieved by dehydration. However, the water activity can also be lowered by other processes known in the art. For example, to reduce the water activity, food additives conventionally used for this purpose such as glycerin, propylene glycol, salt, corn syrup, sugar and the like can be included in the meat and/or meat by-product containing particles in conventional amounts.

Commercially available meats and/or meat by-products having the above low water activity can be used for the meat and/or meat by-product particle ingredient of the invention. Microbiological stability of the meat and/or meat by-products can also be achieved even at water activities above 0.70 by the use of antimycotics together with either bacteriostats or sterilizing gases conventionally used in the art for this purpose. Exemplary of the antimycotics which can be used are potassium sorbate, sorbic acid, sodium benzoate and the like. Suitable commercially available meat products and/or meat by-products which can be used are those which are stored without refrigeration and are packaged in a film of no more than 5 g per  $m^2$  per 24 hours water vapor transfer rate.

The substantial absence of color based by the particles containing only meat and/or meat by-product into the biscuit is principally due to the use of meat products wherein the color is formed as part of the protein matrix. In these meat products the protein is present in its least soluble form, namely denatured and coagulated, and therefore the color is also insoluble. Accordingly, bleeding of the meat protein color into the remaining portion of the biscuit cannot take place. The subject of lack of color bleed when farinaceous material and/or

textured vegetable protein is used in place of some of the meat and/or meat by-product is treated below.

Visual awareness of the meat particles is also effected by using meat products having a dark brown denatured meat protein color. Products having a denatured meat protein color as measured by an Agtron reflectance value of 10 or less contrasts excellently with typical biscuit doughs to effect visual awareness.

The term "meat" is understood to apply not only to the flesh of cattle, swine, sheep, goats, horses and whales, but also to other sources of animal protein, such as poultry and fish. The term "meat by-product" refers to those non-rendered parts of the carcasses of slaughtered animals, including but not restricted to mammals, poultry and fish, and includes constituents such as liver, kidney, heart, spleen, tongue, trimmings, lungs and skins, embraced by the term "meat by-products" in the *Official Publication, "Official and Tentative Definitions of Feed Ingredients,"* published by the Association of American Feed Control Officials, Inc., p. 94 (1979). The flesh of some animals, such as fish and poultry may be too light in color to provide sufficient contrast with the biscuit dough so as to enhance visual awareness of the meat particles. In this case, known food colorings can be added to the meat to enhance visual awareness. The meat particles and the meat by-product particles can be used alone or in combination. Each particle may contain both meat and meat by-products from one or more animals.

The preferred particles containing only meat and/or meat by-product particles are particles of dehydrated cured meat and meat by-product, most preferably from beef. Spiced, dehydrated cured meat and meat by-product particles are highly palatable, have an appetizing odor and are particularly preferred for use in the canine biscuits of the invention. The preparation of dehydrated cured meat and meat by-product, spiced or unspiced, is well-known in the art and does not form a part of the invention. Suitable dehydrated cured meat and meat by-product is commercially available and is commonly referred to as jerky, jerked beef or jerked meat.

Commercially available, dehydrated cured meat products which contain more than 35 percent moisture can be dried in a conventional manner to within the above moisture content range.

Known biscuit dough formulations for the preparation of dry soft canine biscuits can be used in the production of the biscuits of the invention. As indicated above, these doughs generally have a water activity of about 0.90 and above upon completion of mixing of the dough ingredients. A suitable dough contains at least one farinaceous material, the predominant one being glutenous, salt, animal fat, flavorings, added vitamins and minerals and an antioxidant, such as those disclosed in U.S. Pat. No. 4,229,485 at column 5, lines 7 to 25 and 37 to 57, a humectant such as sugar, propylene glycol, glycerin, sorbitol and corn syrup, and chemical leavening. The compositions of the invention also preferably contain at least one animal-derived proteinaceous meal such as meat meal, bone meal and fish meal. A preferred biscuit dough for producing the biscuits of the present invention contains about 40 to about 50 percent by weight of wheat flour, about 10 to about 15 percent by weight of sugar (e.g., sucrose), about 5 to 15 percent by weight of humectant, about 3 to about 10 percent by weight of meat meal, about 1 to about 5 percent by weight of chemical leavening, about 1 to about 10 percent by weight of animal fat preserved with BHA,

about 15 to about 25 percent by weight of water, and about 2 to about 5 percent by weight of natural flavors, and vitamin and mineral preblend. More generally, useful biscuit doughs can contain about 15 to about 35 percent by weight of water, about 0.5 to about 10 percent by weight of fat and about 5 to about 20 percent by weight of sugar. Use of the humectant is optional, but is preferred to enhance the softness of the product and to effect less breaking force. Suitable humectants are known in the art and include glycerin, sorbitol, propylene glycol, corn syrup and sugar. Chemical leavening, known in the art can be used. Exemplary thereof is calcium acid phosphate with sodium bicarbonate, and/or ammonium bicarbonate.

The relative amount of the meat and/or meat by-product containing particles and the biscuit dough should be such so as to result in a dried biscuit product wherein the weight percent of the particles is about 3 to about 25 percent by weight, preferably about 5 to about 20 percent by weight, of the final dried biscuit product. Compliance to NRC nutritional requirements is enhanced by even these low levels of the 20 percent minimum protein meat and/or meat by-product particle. Lower or higher levels of the meat particles can be used provided biscuit integrity is maintained, the meat particles do not extend above the surface of the biscuit so as to separate from the biscuit during shipment, the final product remains visually attractive to the consumer, and the product is economical to produce.

In producing the soft, dry canine biscuit of the invention the meat and/or meat by-product containing particles are dry-blended with the solid non-fat portion of the biscuit dough. By incorporating the meat particles into the solid non-fat portion of the biscuit dough, the meat particles are distributed substantially uniformly throughout the final biscuit product. The portion of the particles at the surface of the biscuit are visually apparent as discrete particles. Particles substantially below surface however are also of sufficient size and integrity to be visually apparent as discrete particles upon breaking the biscuit in two, for example.

All mixing can be at 20 to 100 rpm. The dry-blending step is typically at room temperature for a period of time of about 3 minutes to about 10 minutes so as to obtain a uniform mixture of the meat and/or meat by-product containing particles and non-fat portion of the biscuit dough. The dry-blended mixture is then mixed with the hot water plus optional humectant to form a first stage dough. This methodology minimizes the occurrence of meat and/or meat by-product containing particles substantially above and on the final biscuit surface. As a result, the opportunity for meat and/or meat by-product particles loss from physical abuse during transit is reduced. The water which is admixed with the dry-blended mixture is typically at a temperature of about 65° F. to about 150° F. The hot water and the optional humectant is added, with mixing, over a period of time of about 3 minutes to about 10 minutes to form the first stage dough. Then, the fat portion of the biscuit dough is admixed with the first stage dough to form the final stage dough. The fat portion is added at a temperature at which it is at least fluid, typically at about 100° F. to about 150° F. The fat portion is mixed for a period of time which is sufficient to form a dough whose homogeneity is visually apparent. A typical final mixing time is about 3 minutes to about 8 minutes.

Formation of the dough is achieved at about atmospheric pressure with mixing of the components being

conveniently achieved in an upright sigma blade mixer or other bakery-type mixers. The various ingredients can be added over a period of time or in a one-shot manner according to the above order of addition. However, melted fat and water plus optional humectant may be added simultaneously and mixed 6 to 12 minutes.

The dough is then formed into pieces by horizontal or vertical extrusion followed by cutting. The cutting is preferably substantially perpendicular to the direction of flow of the extruded dough. Thus, when horizontal extrusion is utilized, the extruded dough is preferably cut substantially perpendicular to the top surface of the oven band. When vertical extrusion is used, the extruded dough is cut preferably substantially parallel to the top surface of the oven band. Suitable die and cutter shapes are those which result in a round, square, rectangular, triangular, tubular, or cylindrically shaped biscuit product and the like. The forming is accomplished at conventional temperatures of ambient to 110° F. and pressures of less than 75 p.s.i. (gauge), used with a horizontal or vertical extruder. An essential or critical feature of the invention is that the forming of the dough pieces is done using low shear and/or low pressure forming or techniques. High shear or high pressure forming will decimate or smear the meat and/or meat by-product containing particles or will cause bleeding or running of any dye used in the particles. The forming pressure is less than 75 p.s.i.g.

The formed pieces are then baked, followed by drying, to achieve a shelf stable product without the need for moisture barrier protection. Baking and drying temperatures and times are those conventionally used in the production of a soft, dry canine biscuit. The pieces are dried to obtain a biscuit having a water activity of 0.70 or less. Typical baking temperatures and times are about 300° F. to about an average of 475° F. for about 20 minutes to about 6 minutes. Drying conditions are typically about 200° F. to about 325° F. for about 25 minutes to about 12 minutes in a forced air dryer. On a weight basis, the moisture content of the final biscuit product is less than or equal to about 15 percent by weight and preferably about 10 to about 12 percent by weight of the final biscuit at 0.70 water activity.

The hardness of the final soft biscuit of the invention as measured in a cracking test on a Dillon dynamometer should be about 5 to about 15 lbs. for a  $\frac{1}{8}$  inch thick sample using a pinpoint tester having a 3/32 inch diameter tip. The tip has a concave bottom with a maximum depth of 1/16 inch. In this test, the hardness reading in pounds is linearly proportional to the sample thickness. Thus, a  $\frac{1}{4}$  inch thick sample should have a hardness of about 3 to 8 lbs. A hard biscuit, as opposed to the soft biscuit of the invention, would have a Dillon dynamometer hardness value of about 30 to about 50 lbs for a  $\frac{1}{4}$  inch thick sample.

The invention also broadly involves a process for preparing dry, cohesive particles, which contain meat and/or meat by-product plus farinaceous material and/or textured vegetable protein, for inclusion in the canine biscuit. The meat in particulate form and/or meat by-product in particulate form is admixed with the farinaceous material in particulate form and/or the textured vegetable protein. The admixture is formed by mechanically working the mass at conditions of elevated temperature above about 212° F. and pressure for a time sufficient to convert the mass into a flowable substance and extruding the flowable substance through a restricted orifice. The extruder is particulated into

particles and the particles are dried to form said dry, cohesive particles.

The particles can have up to 99 percent by weight, preferably from 10 to 80 percent by weight, and most preferably 33 to 68 percent by weight, of the meat and/or meat by-product replaced by the farinaceous material and/or textured vegetable protein. In some instances all of the meat and/or meat by-product can be replaced by the farinaceous material and/or textured vegetable protein. The inclusion of the non-meat material in the particles provides a significant cost reduction as compared to all meat and/or meat by-product particles. Particles of meat and/or meat by-product plus farinaceous material plus textured vegetable protein which are stable, cohesive and have particle integrity as such or in a biscuit, are unexpected to the art.

Except as set out herein, the information herein containing the particles containing only meat and/or meat by-products and the soft dough and biscuits containing such particles applies to the particles containing meat and/or meat by-product plus farinaceous material and/or textured vegetable protein, and the soft dough and biscuits containing such particles.

As used herein, the phrase "farinaceous material" means those grain foodstuffs containing a preponderance of starch or starch-like material. Examples of useful farinaceous grain materials are wheat, corn, oats, rye, barley, milo, rice, other cereal grains and starch from such cereal grains. The useful forms are in particles form, such as the farinaceous meals or flours obtained upon grinding cereal grains such as corn, oats, wheat, milo, barley, rice and the various milling by-products of the cereal grains, such as wheat feed flour, wheat middlings, what mixed feed, wheat shorts, wheat red dog, oat groats, hominy feed, and any other such material. Also included are protein concentrates of farinaceous ingredients such as wheat and corn gluten. Preferably the farinaceous material is wheat and preferably the farinaceous material is used in flour form.

Any texturizable vegetable protein can be used. Examples of useful vegetable proteins which can be textured are soybeans, soy protein isolates, soy protein concentrates, cottonseed protein isolates, peanuts, peanut protein isolates, sunflower seed, lentils, sesame, rapeseed, safflower seed, peanut protein concentrates, and other vegetable oil seeds and beans. The vegetable proteins are used in particulate form such as meal and flour. Preferably the vegetable protein is soy (preferably in flour form). The vegetable protein is texturized during treatment (forming) of the particle composition in the cooker extruder.

If desired, textured vegetable protein can be used in place of the untextured vegetable protein. Particle forming in such instances can be done using pellet mills and the like.

The farinaceous material and the textured vegetable protein can be used separately or in combination.

A food-pet food grade dye or colorant is preferably used to dye the farinaceous material and/or textured (or texturizable) vegetable protein. Preferably an artificial or synthetic food grade dye is used in combination with drug and cosmetic dyes approved for use in pet foods. Examples of useful pet food dyes are brown and black iron oxide. The main criterion of a useful food-pet food grade dye within the scope of the invention is that the food-pet food grade dye has not run or bleed (at least to any degree visible by the human eye) in final soft biscuit. A food-pet food grade dye should be used which

has a very high degree of fastness for the farinaceous material and/or textured vegetable protein. The water-soluble food-grade dyes can be used as such or can be used emulsified in oil or fat to color the farinaceous material and/or textured vegetable protein.

When preparing a particle containing meat and farinaceous material, preferably the particle composition contains 27 to 32 percent by weight (most preferably about 29 percent by weight) of meat, 45 to 60 percent by weight (most preferably about 51 percent by weight) of farinaceous material, 10 to 20 percent by weight (most preferably about 14 percent by weight) of proteinaceous-flavoring premix, 2 to 8 percent by weight (most preferably about 5.5 percent by weight) of seasoning and 0.1 to 2 percent by weight (most preferably about 0.5 percent by weight) of colorant. The proteinaceous-flavoring premix preferably containing 40 to 65 percent by weight (most preferably about 54 percent by weight) of protein, usually soy, and 35 to 60 percent by weight (most preferably about 46 percent by weight) of flavorant(s). The particle composition can optionally contain up to about 10 percent by weight, generally 5 to 10 percent by weight, of fat.

When preparing a particle containing meat and vegetable protein preferably the particle composition contains 27 to 32 percent by weight (most preferably about 29 percent by weight) of meat, 60 to 70 percent by weight (most preferably about 65 percent by weight) of vegetable protein, 2 to 8 percent by weight (most preferably about 5.5 percent by weight) of seasoning and 0.1 to 2 percent by weight (most preferably about 0.5 percent by weight) of colorant. The particle composition can optionally contain up to about 10 percent by weight, of fat.

Preferably the particulated meat is prepared by particulating frozen meat, and preferably the particulating is achieved by chopping and the grinding the frozen meat.

In one embodiment all of the ingredients are thoroughly admixed for example in a blender. Preferably 40 the ingredients are preconditioned during mixing in a blender which has a jacketed heater or a steam injector. The mixture is fed into a hopper of a cooker extruder.

In another embodiment the meat, about half of the seasoning and the optional fat are thoroughly admixed 45 for example in a blender. Preferably such first mixture is preconditioned during mixing in a blender which has a jacketed heater or a steam injector. The other half of the seasoning and the remainder of the ingredients are mixed to form a second mixture. The first and second 50 mixtures are separately and simultaneously fed into a hopper of a cooker extruder. The two mixtures are mixed by the action of the extruder. Instead of using the second mixture as such, the ingredients of the second mixture can be separately fed into the hopper.

The blended mixture is then extrusion cooked at conditions of elevated temperature and pressure at about 212° F. to about 400° F. and about 15 psig to about 300 psig respectively. The process of this invention may be practiced in a conventional cooker extruder device. 60 The rotating screw of the extruder device creates a high pressure on the material mixed in the extruder. It is believed that the particular material changes form until it finally flows in a generally fluent manner, even squeezing around the outer periphery of the screw in a 65 recirculating fashion column to cause a severe mechanical working of the substance. The pressures in the extruder are elevated to about 100 psig and typically will

fall within the range of 100 to 200 psig. All of the pressure and the high temperatures result from the friction between flowing products and components of the extruder. During the extrusion operation, cooling water is passed through the rear and forward jacket for temperature control. The mixture is converted to a flowable substance which emerges from the nozzle of the extruder.

The unexpanded extrudate has a bulk density of about 30 lbs. per cubic foot. (A fully expanded extrudate would have a bulk density of about 5 lbs. per cubic foot.) When the particle composition contains vegetable protein as replacement for part or all of the meat and/or meat by-product, preferably the extrudate is partially expanded, having a bulk density of about 15 to about 20 lbs. per cubic foot. Partial expansion is achieved by conventional extruding techniques.

The extruder material is cut into pieces or particles of having a diameter or granulation of between about  $\frac{1}{8}$  inch and about  $\frac{1}{4}$  inch, preferably  $\frac{3}{16}$  inch. The final biscuit will have particles approximately in this size range too. Mixtures of particles within the size range or particles having a given size within this range can be used. The extruded material can be particulated by any suitable means, but preferably staggered cutting blades are used which are located very close to the extruder die.

The extruded particles can be dried or can be dehydrated by known methods to achieve a moisture content of less than about 35 percent by weight. Dehydration also reduces the water activity of the meat and/or meat by-products. Preferably the particles are dehydrated to about 12 to 20 percent by weight water which results in a water activity for the meat of about 0.7 and lower.

The dried particle can be weighed and bagged for storage until usage. The dried particles are shelf stable without refrigeration prior to incorporation into the soft biscuit. The dehydrated particles, spiced or unspiced are highly palatable, have an appetizing odor and are particularly preferred for use in the soft canine biscuits of the invention. The dried particles do not smear into the soft biscuit dough and retains its integrity through production of the final soft product. The particle color does not substantially bleed into the soft biscuit dough.

The invention is further illustrated in the following examples wherein all percentages, parts, ratios and proportions are by weight and all temperatures are in degrees Farenheight unless otherwise indicated.

#### EXAMPLE 1

In this example, spiced dehydrated cured beef granules having a moisture content of about 15 percent by weight, a granulation between  $1/32$  of an inch and  $\frac{1}{4}$  inch, and having a dark brown denatured meat protein color of Agtron reflectance value of 10 or less were used. The spiced hydrated cured meat granules were obtained by granulating dehydrated cured meat having the composition:

Dehydrated Cured Meat	Pounds
Meat By-Products	650
Meat	268
Natural Flavors	1
Spices	29
Cure (Sodium Nitrite)	1
Potassium Sorbate	0.5

-continued

Dehydrated Cured Meat	Pounds
	949.5

Then, 150 pounds of the spiced dehydrated cured meat granules were combined with the non-fat solids portion of a soft biscuit dough, the fat portion of the soft biscuit dough and water plus humectant to form a dough in accordance with the process of the invention. The ingredients, amounts, and the process for making the biscuits were:

Biscuit and Meat Chips	Pounds
Wheat Flour (soft flour of about 9% by weight protein)	400
Sugar	117
Glycerin (humectant)	100
Dehydrated Cured Meat	150
Skim Milk Powder	16
Meat Meal	36
Chemical Leavening	17
Salt	4
Animal Fat Preserved with BHA	75
Natural Flavors	33
Vitamin and Mineral Preblend	18
Color	1
Water	200
	1167 pounds

The dehydrated cured meat was dry-blended with the solid non-fat portion of the biscuit dough in an upright sigma blade mixer at 20 rpm for 10 minutes. Then the 200 pounds of water, at a temperature of 150° F. plus the 100 lbs of glycerin at ambient temperature were added together with 140° F. fat to the preblend and mixed for 6 minutes to form the dough. The dough was then machined on a horizontal extruder through dies measuring  $\frac{1}{8}$  inch in diameter followed by vertical cutting into  $1\frac{1}{4}$  inch length cylinders. The formed pieces were then baked in a band oven for 8 minutes followed by drying at 250° F. for 20 minutes in a band dryer to achieve dry, soft, shelf stable, canine biscuits having a Dillon dynamometer hardness reading of about 4 to 11 for the  $\frac{1}{4}$  inch thick sample. The baking temperatures in the band oven were:

Band Oven Baking Temperatures	Zone
530° F.	1
530	2
550	3
300	4
300	5
300	6
Off	7
Off	8
Off	9

This product was dump-packed into a carton without the need for moisture barrier protection.

The hardness tests on the product were performed using a Dillon hynamometer as described above.

#### EXAMPLE 2

In this example, spiced dehydrated meat granules containing farinaceous material was prepared. The formulation has the following composition:

Ingredients	Percent
Meat	29
Farinaceous material	51
Proteinaceous/flavoring premix	14
Seasoning	5.5
Coloring	0.5
	100 percent.

10 The proteinaceous/flavoring premix contained 54 percent protein (soy) and 46 percent flavoring. The composition further contained 7 percent of fat.

15 The meat was prepared from frozen meat (beef) which was chopped and ground. The farinaceous material was in flour form; the proteinaceous/flavoring agent was also in particle form. The color was synthetic brown food grade and brown pet food grade iron oxide dyes that had good fastness for the non-meat ingredients. All of the ingredients were thoroughly mixed (blended together) using a blender. Steam was injected into the mixture as it was blended to precondition it. The mixture was fed into the hopper of a cooker extruder.

20 The cooker extruder was a conventional cooker extruder having steam and water jackets. Cooling water at room temperature was passed through the cooling jackets. The screw in the extruder was rotated at 165 rpm. The extruder cooked and formed the material which was continuously passed through it. The protein in the material texturized by the heat, pressure, shear, etc. The material was continuously passed through the extruder die and was the extrudate cut into  $3/16$  inch pieces using staggered cutting blades. The extrudate was not expanded and had a bulk density of about 30 lbs. per cubic foot. 95 percent of the particles passed through a  $-4$  U.S. mesh screen and stayed on a  $+14$  U.S. mesh screen. The other 5 percent was fines. The collected particles were dried to a moisture content of 14 percent by weight. The dried particles were cohesive, appetizing in appearance and color and stable when handled. The dried particles were weighed and bagged.

25 Some of the dried particles were then put into a soft dough like the one in Example 1 using the procedure of Example 1. The soft dough and particles were then formed as in Example 1 into various shapes, and baked and dried as in Example 1 to form a dry, soft, shelf stable, ( $\frac{1}{4}$ -inch thick) canine biscuits. The particles in the dried final biscuit visibly discrete, had not smeared and did not show any color bleed.

#### EXAMPLE 3

In this example, spiced dehydrated cured meat granules containing textured soy protein was prepared. The formulation had the following composition:

Ingredients	Percent
Meat	29
Vegetable protein (soy)	65
Seasoning	5.5
Color	0.5
	100 percent.

30 The composition further contained 7 percent fat.

35 The meat was prepared from frozen meat (beef) which was chopped and ground. The farinaceous material was in flour form; the proteinaceous/flavoring agent was also in fine particle form. The color was a

synthetic brown food and pet food grade dyes that had good fastness for the non-meat ingredients.

The meat, half of the seasoning and optional fat were thoroughly mixed in a blender having a hot water jacket, to form a first mixture. The other half of the seasoning and the rest of the ingredients were mixed, to form a second mixture. The first and second mixtures were separately and simultaneously fed into the hopper of a cooker extruder.

The cooker extruder was a conventional cooker extruder having steam and water jackets cooling water at room temperature was passed through the cooling jackets. The screw in the extruder was rotated at about 450 rpm. The extruder cooked and formed the material, which was continuously passed through it. The vegetable protein in the mixture was texturized by the heat, pressure, shear, etc. The material was continuously passed through the extruder die and was the extrudate cut into 3/16 inch pieces using staggered cutting blades. The extrudate was partially expanded (using a proper size die to achieve such upon exit to atmospheric pressure) and had a bulk density of about 20 lbs. per cubic foot. The collected particles were dried to a moisture content of 14 percent by weight. The dried particle were cohesive, appetizing in appearance and color and stable when handled. The dried particles were weighed and bagged.

Some of the dried particles were then put into a soft dough like the one in Example 1 using the procedure of Example 1. The soft dough and particles where then formed as in Example 1 into various shapes, and baked and dried as in Example 1 to form dry, soft, shelf stable,  $\frac{1}{4}$ -inch thick, canine biscuits. The particles in the dried final biscuit were visibly discrete, had not smeared and did not show any color bleed.

What is claimed is:

1. Dry soft canine biscuit consisting essentially of discrete, visually apparent dehydrated particles, which contain (i) meat and/or meat by-product and (ii) farinaceous material and/or textured vegetable protein distributed substantially uniformly throughout said biscuit, the remaining portion of said biscuit being substantially free of meat particle color and containing a major portion of at least one farinaceous material, said biscuit having a water activity of 0.70 or less, and a water content of 15 weight percent or less, based upon the total weight of said dry soft canine biscuit, said particles being present in an amount of about 3 to about 25 weight percent, based on the total weight of said dry soft canine biscuit, said particles having a water activity which is equal to or less than the remaining portion of said biscuit, and said particles being non-expanded or partially expanded, of sufficient size to be discrete and visually apparent, substantially of a size which passes through a U.S. No. 4 Mesh screen and stays on a U.S. No. 14 Mesh screen, and having a water content of 12 to 20 weight percent, based on the total weight of said dehydrated particles whereby said biscuit having been made from a soft dough containing humectant.

2. A dry soft canine biscuit as claimed in claim 1 wherein said particles are non-expanded.

3. The dry soft canine biscuit as claimed in claim 2 wherein said remaining portion of said biscuit is non-expanded.

4. The dry soft canine biscuit as claimed in claim 1 wherein said particles are partially-expanded and have a bulk density of up to about 20 pounds per square foot.

5. The soft dry canine biscuit as claimed in claim 1 wherein the farinaceous material is a glutenous farinaceous material and wherein said remaining portion of said biscuit contains at least one animal-derived proteinaceous meal.

6. Dry soft canine biscuit consisting essentially of discrete, visually apparent dehydrated particles, which contain (i) meat and/or meat by-product and (ii) farinaceous material and/or textured vegetable protein distributed substantially uniformly throughout said soft dry canine biscuit, the remaining portion of said dry soft canine biscuit being substantially free of meat particle color and containing a major portion of at least one farinaceous material, said dry soft canine biscuit having a water activity of 0.70 or less, and as water content of 15 weight percent or less, based upon the total weight of said dry soft canine biscuit, said particles being present in an amount of about 3 to about 25 weight percent, based on the total weight of said dry soft canine biscuit, said particles having a water activity which is equal to or less than the remaining portion of said biscuit, said soft dry canine biscuit being shelf stable, said soft dry canine biscuit having said particles present as discrete visually-apparent particles distributed substantially uniformly throughout, some of said discrete visually-apparent particles being visible on the surface of said dry soft canine biscuit, and said particles being non-expanded or partially expanded, and of sufficient size to be discrete and visually apparent, substantially of a size which passes through a U.S. No. 4 Mesh screen and stays on a U.S. No. 14 Mesh screen, and having a water content of 12 to 20 weight percent, based on the total weight of said dehydrated particles.

7. The dry soft canine biscuit as claimed in claim 6 wherein said particles are non-expanded.

8. The dry soft canine biscuit as claimed in claim 7 wherein said remaining portion of said biscuit is non-expanded.

9. The dry soft canine biscuit as claimed in claim 6 wherein said particles are partially-expanded and have a bulk density of up to about 20 pounds per square foot.

10. The soft dry canine biscuit as claimed in claim 6 wherein said particles are cohesive and have particle integrity.

11. The soft dry canine biscuit as claimed in claim 6 wherein said particles contain up to 99 weight percent of said farinaceous material and/or textured vegetable material.

12. The soft dry canine biscuit as claimed in claim 6 wherein said textured vegetable material is textured soy protein.

13. The soft dry canine biscuit as claimed in claim 6 wherein said farinaceous material is wheat.

14. The soft dry canine biscuit as claimed in claim 6 wherein said dry soft canine biscuit has a hardness equivalent to a reading of 5 to 15 lbs. for a biscuit having a thickness of about  $\frac{1}{4}$  inch measured on a Dillon dynamometer having a pinpoint tester with a 3/32 inch diameter tip having a concave bottom.

15. The soft dry canine biscuit as claimed in claim 6 wherein said particles have a dark brown denatured meat protein color of Agtron reselectance value of 10 or less.

16. The soft dry canine biscuit as claimed in claim 6 wherein said dry soft canine biscuit is tubular shaped and a farinaceous filler is contained within said tubular shaped biscuit.

17. The soft dry canine biscuit as claimed in claim 6 wherein said particles contain a food coloring and wherein the remaining portions of said biscuit are substantially free of said food coloring.

18. The soft dry canine biscuit as claimed in claim 6 5

wherein the farinaceous material is a glutenous farinaceous material and wherein said remaining portion of said biscuit contains at least one animal-derived proteinaceous meal.

\* \* \* \* \*

Exhibit C



US005407661A

## United States Patent [19]

Simone et al.

[11] Patent Number: 5,407,661

[45] Date of Patent: \* Apr. 18, 1995

## [54] PET CHEW PRODUCT HAVING ORAL CARE PROPERTIES

[75] Inventors: Alexander J. Simone, Somerset, N.J.; John J. Hefferren, Lawrence; Michael S. Hand, Maple Hill; Gordon Huber, Sabetha, all of Kans.

[73] Assignee: Colgate-Palmolive Company, Piscataway, N.J.

[\*] Notice: The portion of the term of this patent subsequent to Mar. 22, 2011 has been disclaimed.

[21] Appl. No.: 118,369

[22] Filed: Sep. 8, 1993

## Related U.S. Application Data

[63] Continuation of Ser. No. 822,241, Jan. 17, 1992, Pat. No. 5,296,209.

[51] Int. Cl. 426 807; 426 805; A61K 7/16; A61K 9/20; A61K 31/715; A61K 7/26

[52] U.S. Cl. 424/49; 424/401; 424/439; 424/442; 424/57; 426/807; 426/805

[58] Field of Search 424/49-58, 424/401, 439, 442, 447; 426/807, 805, 658, 648, 635, 630, 623, 618, 578, 560, 549, 3

[56]

## References Cited

## U.S. PATENT DOCUMENTS

4,276,311	6/1981	Burrows et al.	426/805
4,515,772	5/1985	Parran et al.	424/57
4,624,856	11/1986	Vanderveer et al.	426/549
4,806,340	2/1989	Gaffar et al.	424/52
4,822,599	4/1989	Mitra	424/52
4,885,155	12/1989	Parran et al.	424/52
4,906,456	3/1990	Gaffar et al.	424/52
4,925,654	6/1990	Gaffar et al.	424/52
4,931,273	6/1990	Gaffar et al.	424/52
4,966,771	10/1990	Gaffar et al.	424/52
4,999,184	3/1991	Parran et al.	424/52
5,000,940	3/1991	Staples	424/57
5,000,943	3/1991	Scaglione et al.	424/57
5,000,973	3/1991	Scaglione et al.	426/549
5,015,485	5/1991	Scaglione et al.	426/94
5,296,209	3/1994	Simone et al.	424/49

Primary Examiner—Shep K. Rose

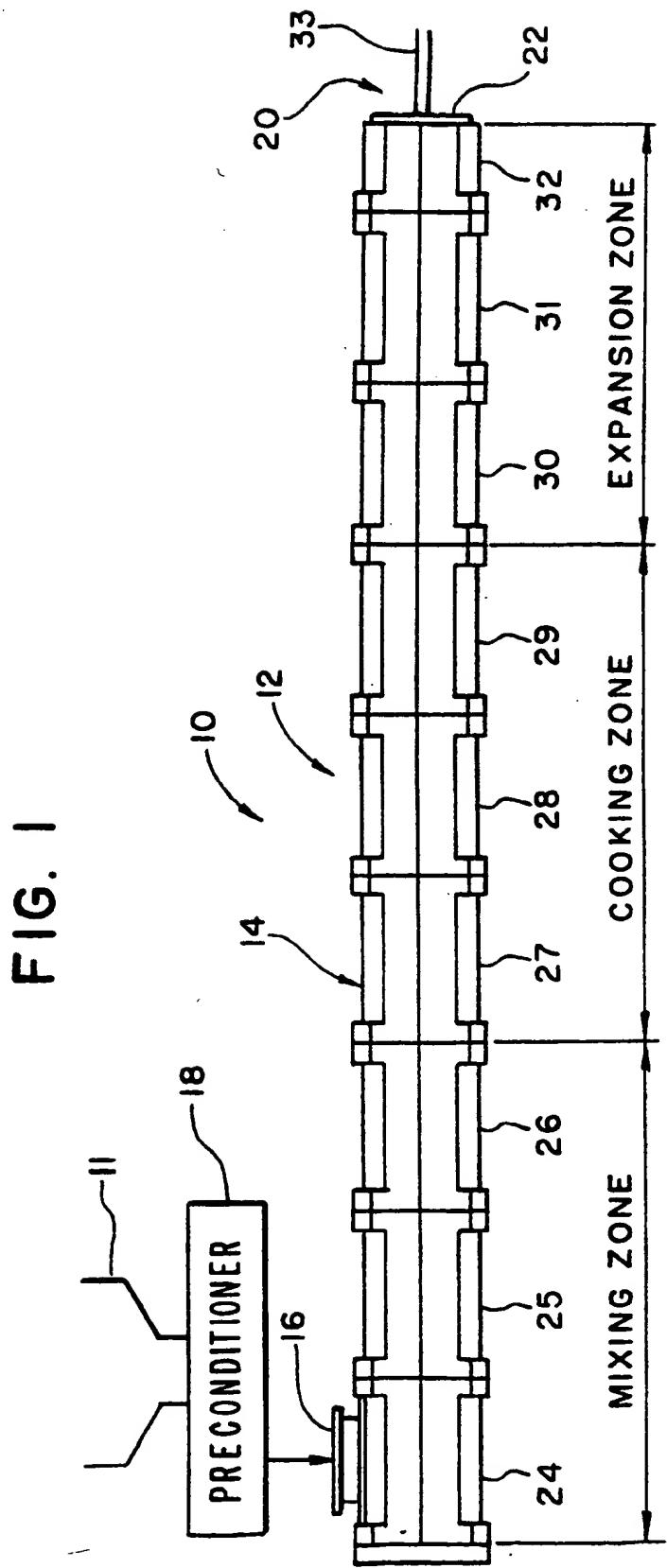
Attorney, Agent, or Firm—Paul Shapiro; Robert C. Sullivan

[57]

## ABSTRACT

An edible pet chew product having a flexible cellular matrix in which is contained a cellulosic fibrous material such as corn cob fractions having a mechanical cleansing function, which when chewed by the pet, effects a reduction in plaque, stain and tartar on the pet's teeth. An oral care additive may be incorporated in the matrix to inhibit dental problems, the composition of the cellular matrix being substantially inert to the oral care additive.

32 Claims, 1 Drawing Sheet



## PET CHEW PRODUCT HAVING ORAL CARE PROPERTIES

This is a Continuation of application Ser. No. 07/822,241, filed Jan. 17, 1992, now U.S. Pat. No. 5,296,209.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

This invention relates to an edible animal chew product having a flexible, inert cellular matrix containing a cellulosic fibrous material. The edible product, when chewed by animals such as dogs and cats, reduces plaque, stain and tartar.

### DESCRIPTION OF THE PRIOR ART

Animal pets, such as dogs and cats, like their human counterparts, are subject to dental health problems. These problems can be traced to the formation of bacterial plaque which forms on the exterior surface of teeth. Plaque is an invisible, sticky film of bacteria, salivary proteins and polysaccharides which is not easily washed away. Plaque is now generally recognized as the main culprit of poor oral health. Bacteria that produce the acid for the caries process are held to the tooth surface by the plaque matrix as well as other bacteria which cause redness and swelling (gingivitis). The presence of these bacteria, if left untreated, may spread to cause malodor, periodontal disease, gingival pockets and bone loss.

Dental calculus, or tartar, is the result of the thickening and hardening (mineralization) of dental plaque. Tartar which is not easily removed accumulates on the tooth surface, mainly at the gingival margin opposite the salivary glands. It is a hard mineral deposit containing predominantly calcium and phosphate, very tightly bound to the tooth surface. Once it is formed, tartar is virtually impossible to remove except by a dental professional. Tartar can become unsightly if growth is left unimpeded, and elimination is desirable as the porous surface of the calculus will be covered by a thin layer of unmineralized plaque which can cause constant irritation of the gums and can trigger other problems once calculus is formed below the gum line.

Commercial animal pet foods do not provide sufficient surface cleaning to teeth to provide for plaque removal from the animal's teeth necessary for optimum dental health.

A variety of products are manufactured to provide animal pets with objects to chew or gnaw. They are intended to provide the pet with exercise for the teeth to maintain a healthy condition satisfying a need which arose when the natural pet food, raw meat, was replaced with processed pet foods. Rawhide strips knotted on the ends to resemble bones, for example, provide abrasion for cleaning teeth by removing tartar and massaging the gums, which is not provided by the typical canine dog food. The rawhide dog chews are expensive, and the indigestible leather fragments swallowed by the dogs frequently cause severe gastrointestinal blockage or diarrhea.

European patent 272,968 discloses a chewable product for dogs and other domestic animals wherein certain aqueous solutions of oral care agents, e.g., sodium fluoride (anti-caries agent), sodium benzoate (anticalculus agent) and bromochlorophene (antimicrobial/anti-plaque agent) are used to soak rawhide, beef tendon, or

ligament. The solution treated product is then dried whereby the oral care agents are absorbed into the surface of the product.

U.S. Pat. Nos. 5,000,940 and 5,000,943 disclose baked dog biscuits containing an inorganic pyrophosphate salt, e.g., tetrasodium pyrophosphate, which when chewed and/or eaten by dogs cause a reduction in tartar accumulations on their teeth.

The oral care agents incorporated in the pet food products of the prior art have either limited efficacy in oral care, or are incompatible and deactivated by the ingredients found in the products into which these agents are incorporated. For example, anti-tartar pyrophosphate salts incorporated in pet food products containing an excess of polyvalent cations, and particularly calcium, are rendered inactive by the calcium ion interacting with the pyrophosphate rendering it insoluble and thereby inactive.

Attempts to incorporate other oral care agents such as fluoride compounds in animal chews were unsuccessful as these compounds were also incompatible and unstable with ingredients from which the pet food product was fabricated.

A further disadvantage of the prior art pet oral care products is that they are baked products which are hard and brittle and, although abrasive and initially effective to remove plaque from teeth, quickly lose their effectiveness when chewed because rapid fracture of the product leads to loss of contact of the product with the teeth.

There is therefore a need in the pet food field for a product which is edible and consumable without gastrointestinal complications and effective to remove plaque and to inhibit the formation of tartar in pet animals such as dogs and cats.

### SUMMARY OF THE INVENTION

This invention is directed to an edible animal chew product having a flexible cellular matrix in which is incorporated a cellulosic fibrous material having a mechanical cleansing function which, when chewed by the animal, reduces tartar, stain and plaque on the animal's teeth through a physical cleansing action without causing gastrointestinal distress. An oral care agent may be incorporated in the matrix to inhibit dental health problems. When chewed, the flexible, cellular product does not easily fracture and the drag created as the product is chewed by the animal increases the time that the product is retained in the animal's mouth cavity and in contact with its teeth. The product is extruded from ingredients which are inert to oral care additives to assure maximum bioavailability of the additives. The extruded product preferably contains starch, cellulosic fibers, humectant, proteinous binder and one or more oral care additives.

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

In general, the edible chew product of the present invention is made by admixing a starch containing ingredient, a cellulosic fibrous material, humectant, and proteinous binder and oral care additives such as tartar control and anticaries additives and then subjecting the moistened admixture to mechanical working in an extruder at an elevated temperature so as to extrude an expanded product having a flexible, cellular matrix.

In the preparation of the chew product of the present invention, the solid components of the chew product;

namely cellulosic fibrous material, starch, and proteinous binder together with any oral care additive, are first admixed together.

The cellulosic fibrous component which provides mechanical cleansing ability to remove dental plaque, stain, tartar and other *materia alba* accumulating on the animal's tooth surfaces when the product is chewed by the animal is a cellulosic fibrous material including corn cob fractions, cellulose fiber and other plant fibers or microbial polysaccharides. Corn cob fractions are preferred.

Although the cellulosic fibrous materials are not digested by the pet, the pet's digestive system is capable of handling such fibers by passing them through its system substantially unchanged. In fact, the cellulosic fibrous materials provide increased roughage and bulk so as to assist the pet in the digestion of food.

Generally, cellulosic fibrous materials such as corn cob fractions are included in the chew product at a concentration of about 20 to about 50% by dry weight of the chew product and preferably about 25 to about 35% by weight. Corn cob fractions generally range in particle size from about 5 to about 1000 microns and preferably about 20 to about 250 microns.

Corn cob residues from both the woody and shaft portions of the cob are compatible with oral care additives such as tartar control additives including inorganic alkali pyrophosphate salts which are incorporated in the chew product. Corn cob fractions serve the additional function of being moisture absorbent contributing resiliency and flexibility to the chew product. Further, the corn cob fractions also provide a greater range of earth tones and contribute a positive aroma to the chew product.

The term "starch" as used herein includes within its meaning amyliaceous hydroxylates containing mono-, di-, tri- and polysaccharides and mixtures thereof such as those derived from wheat, corn or like cereals or tubers. Starch forms a matrix superstructure into which the oral care additives including cellulosic fibrous particles and oral care additives are suspended.

During the fabrication of the chew product by mechanical working in an extruder, starch materials function as an expansion medium. The gelatinization of the mechanically worked product mass due to the heat and moisture introduced during the extrusion process swells the starch granules releasing amylose and amylopectins to thicken and form a gelatinized matrix. The proteinous binder undergoes a similar gelatinization reaction whereby the starch and binder join to form the cellular matrix structure.

Suitable starch materials useful in the preparation of the chew product of the present invention include wheat starch, corn starch, oat starch, rice starch and other complex carbohydrates. The starch is included in the chew product at a concentration of about 30 to about 60% by dry weight and preferably about 40 to about 55% by dry weight of the product.

The proteinous binder incorporated in the chew product has an adhesive effect and binds together the solid particles to form a cohesive, integral mass when the ingredients are heated and extruded to form the expanded cellular product.

Proteinous binder materials suitable for use in the preparation of the chew products of the present invention include collagen and gelatin. Collagen derived from the digestion of beef bones is preferred in the practice of the invention. Gelatin derived from both

pork skin and animal bones is also a preferred binder material. The binder material is used in the preparation of the chew product of the present invention at a concentration of about 5 to about 20% by weight of the chew product and preferably about 8 to about 10% by weight. Collagen and gelatin materials also contribute to the flexible texture of the extruded cellular matrix chew product.

Oral care additives that may be incorporated in the chew products of the present invention include tartar control additives such as inorganic pyrophosphate salts including dialkali or tetra-alkali metal pyrophosphate salts such as  $Na_4P_2O_7$ ,  $K_4P_2O_7$ ,  $Na_2K_2P_2O_7$ ,  $Na_2H_2P_2O_7$ , and  $K_2H_2P_2O_7$  and combinations thereof. The tartar control additives are incorporated in the chew products of the present invention at a concentration effective to inhibit tartar formation on the animal's teeth. Suitable concentrations of the pyrophosphate salts range from about 0.5 to about 15% by dry weight and preferably 1.0 to about 10% by dry weight of the chew product.

It is further preferred that a combination of alkali metal pyrophosphate salts be used and particularly a combination of potassium and sodium pyrophosphates at a weight ratio of about 5:1 to 1:1. A weight ratio of about 3:1 is especially preferred.

In addition to pyrophosphate tartar control additives, fluoride containing salts may also be incorporated in the chew product to inhibit phosphate enzymes that hydrolyze and degrade the pyrophosphate salts whereby the tartar control efficacy of these salts is otherwise reduced.

The fluoride-providing salts used in the practice of the present invention are characterized by their ability to release fluoride ions in water and by substantial freedom from reaction with the other ingredients of the chew product. Among these materials are inorganic salts, for example, sodium fluoride, potassium fluoride, a tin fluoride such as stannous fluoride or stannous chlorofluoride, and sodium monofluorophosphate. Alkali metal and tin fluorides, such as sodium fluoride, stannous fluoride, sodium monofluorophosphate and mixtures thereof, are preferred.

When included in the chew product, any suitable minimum amount of the fluoride salt may be used, but it is preferable to employ sufficient salt to release from about 0.05% to 1%, and preferably about 0.1% of fluoride ion. Typically, in the cases of alkali metal fluorides and stannous fluoride, the salt is present in an amount up to 2% by weight, based on the weight of the product, and preferably in the range of from 0.05% to 0.5% by weight.

Other agents suitable for incorporation in the chew product of the present invention include synthetic anionic linear polymeric polycarboxylates which are employed in the form of their partially or preferably fully neutralized water soluble alkali metal (e.g. potassium and preferably sodium) or ammonium salts. The polycarboxylates, like the fluoride salts, inhibit salivary enzymes which hydrolyze pyrophosphates to an inactive form. Preferred are 1:4 to 4:1 copolymers of maleic anhydride or acid and a polymerizable ethylenically unsaturated monomer, preferably a lower alkyl vinyl ether such as methoxyethylene, having a molecular weight of about 30,000 to about 1,000,000. These copolymers are available commercially from GAF Corporation under the trademark Gantrez, e.g. Gantrez S-97 Pharmaceutical Grade (molecular weight 70,000). The

polycarboxylates are incorporated in the chew product of the present invention at a concentration of about 0.25 to about 4% by weight and preferably about 1.0 to about 3.0% by weight.

To impart flexibility to the chew product, it is advantageous to adjust the moisture content of the chew product so that the final product contains water at a concentration equal to or greater than 12% by weight and preferably 16 to 35% by weight.

A humectant is incorporated in the chew product to enhance the flexible chew texture and retain moisture so as to maintain the texture when the chew is stored at ambient temperatures. The preferred humectants are glycerine and sorbitol. Typically, the humectant is incorporated in the chew product at a concentration of about 1 to 15% by weight and preferably about 4 to about 10% by weight of the product.

Suitable flavoring materials may be employed to enhance the palatability of the chew product of the present invention. Examples of suitable flavoring constituents include garlic, wood smoke, meat, and fish extracts and fermentation residues. suitably, the flavoring agent comprises from about 0.01 to 5 percent by weight or more of the chew product of the present invention and preferably, about 0.8 to about 1.5 percent by weight.

The extruded chew product of the present invention is a solid composition having a cellular matrix and a chewy non-brittle texture which is not readily fractured when chewed by the animal and hence offers the animal the intended teeth cleansing benefits stemming from the mechanical cleansing and other contacts with the cellulosic fibrous particles and contained in the chew product. In addition, as the product does not fracture as the animal gnaws on the product, the product remains in contact with the teeth prolonging the bioavailability of the oral care additives contained therein.

As all the ingredients of the chew product are substantially inert and non-reactive with the oral care additives, they are compatible with the oral care additives so that these additives are stable and retain their efficacy during storage before use.

Due to the presence of relatively high moisture levels in the chew product, preservatives such as sodium benzoate, potassium sorbate, sodium propionate, sorbic acid, or paraaminobenzoic acid esters (parabens) alone and in combination may be incorporated into the product to inhibit mold bacteria, yeast formation and growth. The preservative may be incorporated in the chew product at a concentration in the range of about 0.05 to about 4.0% by dry weight and preferably in the range of about 0.1 to about 0.6% by dry weight.

To prepare the chew product, the starch, humectant, proteinous binder, cellulosic fibrous material and oral care additives are transferred to a steam pre-conditioner and subjected to steam and moisture in order to adjust the moisture content to between about 20 and 50% by weight. The conditioned mixture is then extruded under conditions of elevated temperature and pressure to form a continuous ribbon of expanded cellular product that is segmented into discrete particles or pieces by a rotating knife or other cutting means upon exit of the ribbon from the extruder. The chew particles are then allowed to cool and dry at a controlled temperature, e.g. 65-75° F., to adjust the moisture level to about 10 to about 30% by weight.

#### BRIEF DESCRIPTION OF THE DRAWINGS

In the figure, there is shown one embodiment of an extrusion apparatus 10 which can be used to manufacture the cellular chew product. The extrusion apparatus 10 includes an extruder 12 having a barrel 14 with an inlet 16 located below the outlet of a preconditioner 18; the extruder 12 also having an outlet 20 with a die 22. Hopper 11 is provided to pre-mix the ingredients prior to preconditioning. The barrel 14 as depicted comprises nine barrel sections 24, 25, 26, 27, 28, 29, 30, 31, 32, although the number of barrels may vary without departing from the principles of the present invention. The barrel sections are interconnected to present an elongated bore through the barrel 14 of the extruder 12. Two co-rotating, flighted material advancing screws (not shown) are received in the bore of the barrel and are intermeshed along the majority of the length of the extruder barrel 14 and terminate in the die section 22. The screws feed material to and through the extruder assembly, including a die, at an appropriate flow rate and under appropriate flow conditions. Extrusion apparatus 10 of the type illustrated in the figure is manufactured by Wenger Manufacturing such as the Wenger TX-52 (research extruder) or Wenger TX 80 twin screw (commercial extruder). The pre-conditioner 18 shown in the figure is also manufactured by Wenger Manufacturing, Inc.

In preparing the extruded cellular product of the present invention, using the Wenger TX-80, the solid ingredients from which the chew product is extruded are first pre-mixed in a mixer such as a ribbon mixer and fed to hopper 11. These pre-mixed ingredients include a cellulosic fibrous material such as corn cob fractions, starch, oral care additive, preservative and binder. The pre-mixed solid ingredient is then fed to the preconditioner 18 and admixed with the humectant and other liquid ingredients which are fed directly into the preconditioner 18. In the preconditioner 18 the mixture of ingredients is fed thereto at a rate between 10 and 20 pounds (lbs.)/minute and is further mixed with water which is introduced into the preconditioner at a rate of 0.5 to 4.0 lbs/minute. The temperature of the mixture is raised from ambient to 150° to 200° F. (170° F. being preferred) by the injection of steam into the preconditioner 18 at the rate of 0.5 to 5.0 lbs/minute. Total residence time in the preconditioner 18 generally ranges from 0.5 to 1.5 minutes.

Preconditioning the mixture with steam and water initiates hydration of the binder which is completed by the mechanical working during the extrusion process. The humectant is desirably added after the mixture has been first contacted with the steam/water treatment so as not to compete with the binder for the moisturizing treatment in the preconditioner.

Once the mixture of ingredients and water is introduced into the extruder barrel 14, the mixture is advanced along the length of the barrel 14 by axial rotation of the twin screws. The mixture is sequentially advanced through the extruder and finally through the die 22 at the outlet of the extruder 12, the die 22 having an orifice shaped to yield a ribbon of expanded cellular product. As the mixture passes through the barrel sections 24, 25, 26, 27, 28, 29, 30, 31, and 32, it is mixed, cooked at product temperatures in the range of 200°-280° F. to cause expansion of the extrudate product as it leaves the die 22.

Typically, barrel sections 24, 25 and 26 comprise a Mixing Zone where the moisturized product mixture is introduced and compressed into the extruder barrel 14 at a temperature of 100°-120° F., followed by a Cooking Zone, barrel sections 27, 28 and 29 where the mixture is cooked at a temperature of about 140° to about 200° F. This is followed by an Expansion Zone (barrel sections 30, 31, 32) where the gelatinized mixture undergoes expansion. Thereafter, the product further expands as it is blown out through the orifice of the die 22 as ribbon 33. The blowing out induces the product to further puff or expand to form the desired cellular matrix product.

The pressure within the extruder ranges from about 0 to 100 psi in the Mixing Zone, about 10 to 200 psi in the Cooking Zone and about 100 to 1,000 psi in the Expansion Zone. The residence time in any one zone is about 10 to about 45 seconds and generally about 30 seconds.

The expanded cellular product as it leaves the extruder has a moisture content of about 10 to about 35% water by weight and, preferably, about 15 to about 25% water by weight.

The thickness of the extruded cellular product is controlled so that it has a thickness of about 0.25 to about 0.75 inches upon leaving the extruder die 22. The ribbon of cellular matrix extrudate 33 is then cut and subdivided into longitudinal 1 to 5 inch sections and allowed to cool and dry to a moisture content of about 12 about 35% by weight water.

The invention is further illustrated by the following specific but non-limiting Example.

#### EXAMPLE

A mix for the preparation of a dog chew designated "Chew Product I" was prepared which contained the following ingredients:

Ingredient	Weight %
Wheat Starch	45.42
Corn Cob Fraction*	32.58
Gelatin (225 Bloom)	9.87
Glycerin	4.44
Potassium Sorbate	0.30
Gantrez S-97 (approx. 13% soln)	1.92
K <sub>4</sub> P <sub>2</sub> O <sub>7</sub>	4.00
Na <sub>4</sub> P <sub>2</sub> O <sub>7</sub>	1.38

\*60 mesh fraction. Particle size less than 0.15 millimeter, 90% less than 150 microns. Typical sieve analysis as follows:

mesh	%	mm
>50	0.1	0.30
<50 > 60	2.0	0.25
<60 > 100	55.0	0.15
<100	45.0	<0.15

The wheat starch, corn cob fraction, pyrophosphate salts, and potassium sorbate were fed to the hopper 11, of a Wenger research twin screw extruder (Model No. TX-52) equipped with a preconditioner 18, and processed to obtain an expanded chew product having a flexible cellular matrix. The TX-52 machine was of the type schematically illustrated in the figure and was provided with two rotatable, flighted material advancing screws and had a total of 9 barrel sections and terminated in a rounded rectangular port with rate controlling throttle valve.

This mixture having a moisture content of 10.82% was fed to the preconditioner at a rate of 150.0 pounds per hour. The mixture was raised in temperature to 170° F. by the injection of steam introduced at a rate of 0.070 pounds per minute into the preconditioner. Water was

introduced into the preconditioner at the rate of 0.50 pound per minute. The glycerin and Gantrez ingredients were added to the preconditioner at this point.

Next, the mixture was fed into the inlet 16 of the extruder mixing zone and steam was introduced into the mixture at a rate of 0.080 pounds per minute. The screws of the extruder were rotated at a speed of 380 rpm.

Temperatures of the barrel sections were maintained at 111° F., 111° F., 149° F., 182° F., 151° F. and 212° F. for the second, third, fourth, fifth, sixth, seventh, eighth and ninth barrel sections respectively. Product rate through the extruder was about 200 pounds per hour. The product was extruded as continuous flexible ribbon 1.0 inch wide and 0.25 inch thick having a cellular matrix with a water content of 28.01% by weight. The extrudate ribbon was cut into 1.5 foot sections at the extruder head with a rotating knife. The extrudate sections were allowed to dry at ambient temperature in air for one hour. The air dried extrudate sections were determined to have a moisture content of 20% by weight. The dried extrudate sections were further subdivided into 2.75 inch pieces to prepare the final chew product. The final chew product had a spongy, flexible cellular matrix, light tan in color.

A group of 10 pure-bred beagle dogs (ages 1 to 6 years) were individually fed 4 pieces of the chew product daily together with a diet of a commercial canned dog food sold under the name "Hills Canned Canine Maintenance" by Hills Pet Products, Topeka, Kansas, adequate to maintain the weight of each dog for a one week test period. The dogs were fed the canned dog food at about 8 a.m. and two (2) chews at about 10 a.m. and again at about 3 p.m. The individual piece of chew product each weighed about 5 grams.

In observing the eating style of the dogs, it was noted that although the canned dog food ration tended to be gulped by the dogs, the spongy cellular chew product was chewed repeatedly before being swallowed. This chewing action increased the residence time that the chew product was in the dog's mouth thereby increasing the contact time with the teeth of the corn cob particles and pyrophosphate salts contained in the product.

Prior to the feeding test, each dog had been given a thorough dental prophylaxis to remove existing soft and hard deposits on the buccal surfaces of the maxilla and mandible (a total of 22 teeth per dog).

The teeth of each dog in the group was examined for plaque, stain and tartar upon the completion of the test period.

In this examination, each tooth was divided horizontally into a gingival half (next to the gumline) and an occlusal half (away from the gumline). Plaque was scored visually on the corresponding tooth surfaces after staining with 3% erythrosin solution using the following criteria: 1, plaque coverage of up to 25% of the buccal tooth surface; 2, plaque covering between 25 and 50% of the buccal tooth surface; 3, plaque covering between 50 and 75% of the buccal tooth surface and 4, plaque covering between 75 and 100% of the buccal tooth surface.

The thickness of the plaque was scored as follows: Light = 1, Medium = 2 and Heavy = 3. Coverage and thickness scores for each individual tooth surface were then multiplied, to give a total score for that tooth surface. Gingival and occlusal scores were added for each tooth. All tooth scores were added for each animal,

then divided by the number of teeth scored to give a mean plaque score for the animal. A mean group plaque score was obtained by averaging individual scores of all animals in the group.

Stain was scored visually on the corresponding tooth surfaces after drying the tooth surface with a gentle jet of air using the following criteria; each tooth was divided vertically into 3 segments, mesial, buccal and distal; the coverage and color of the stain in each segment was then graded independently; 1, stain coverage of up to 25% of the (mesial, buccal or distal) surface, 2, up to 50%; 3, up to 75% and 4, up to 100%. The stain color was scored 1,L (light), 2,M (medium) and 3,D (dark). Coverage and thickness scores for each individual tooth surface were then multiplied, to give a total score for that tooth surface. Mesial, buccal and distal segment scores were added for each tooth. All tooth scores were added for each animal, then divided by the number of teeth scored to give a mean stain score for the animal. A mean group stain score was obtained by averaging individual scores of all animals in the group.

Tartar was scored visually for area coverage on the corresponding tooth surfaces in the same manner as stain.

The plaque, stain and tartar scores for this group of dogs which were fed Chew Product I are recorded in Table I below. For purposes of comparison, the procedure of the Example was repeated with the exception that the dogs were not fed the chew product. The results of this test are also recorded in Table I below with the designation "Control".

The procedure of the Example was repeated with the exception that the chew product fed to the dogs was derived from an extrudate which did not contain any pyrophosphate salts. This chew product was designated "Chew Product II". The plaque, stain and tartar scores for the group of dogs fed Chew Product II are also recorded in Table I.

For purposes of further comparison, the procedure of the Example was repeated with the exception that, instead of the chew product of the present invention, the dogs were fed four biscuits of a commercially available baked biscuit product containing a pyrophosphate salt oral care additive. The results of this test are also recorded in Table I below with the designation "Comparison I".

TABLE I

Chew Product	Mean Group Plaque Score	Mean Group Stain Score	Mean Group Tartar Score
CHEW PRODUCT I	5.59	1.26	2.43
CHEW PRODUCT II	6.77	2.35	3.49
COMPARISON I	8.34	3.24	4.54
CONTROL	8.87	3.60	5.10

The above results show that the chew product of the present invention, namely Chew Products I and II, is significantly effective in reducing plaque, stain and tartar in dogs, especially when compared to the control as well as the comparative chew product.

Based on the mean group scores of Table I, the percent reduction obtained in plaque, stain and tartar as obtained with the chew products of the present invention (Chew Products I and II) or the commercial baked product compared to not feeding the dogs a chew product, is summarized in Table II below.

TABLE II

	% REDUCTION		
	PLAQUE	STAIN	TARTAR
CHEW PRODUCT I	37.0	65.0	52.4
CHEW PRODUCT II	23.7	34.7	31.6
COMPARISON I	6.0	10.0	11.0

The data recorded in Table II demonstrate the significantly greater reduction in plaque, stain and tartar obtained with the chew product of the present invention when compared to a commercial baked product containing a pyrophosphate salt oral care additive.

What is claimed is:

1. A composition to be chewed by an animal for removing plaque, tartar and stain from the teeth of the animal, which composition comprises an edible, solid unbaked extrudate product having a chewable, flexible cellular matrix in which is incorporated an effective mechanical cleansing amount of a cellulosic fibrous material, water to adjust the moisture concentration equal to or greater than 12% by weight and a humectant at a concentration of about 1 to about 15% by weight, said moisture imparting flexibility to the composition and retaining moisture so as to maintain the texture when the composition is stored.
2. The composition of claim 1 in which an effective amount of a pyrophosphate salt tartar control oral care additive is incorporated in the cellular matrix, the cellular matrix being substantially inert to the oral care additive.
3. The composition of claim 1 wherein the cellular matrix is comprised of a starch.
4. The composition of claim 1 wherein the cellular matrix has incorporated therein a proteinaceous binder.
5. The composition of claim 2 wherein the oral care additive is an alkali metal pyrophosphate salt.
6. The composition of claim 5 wherein the alkali metal pyrophosphate salt is a mixture of potassium and sodium pyrophosphates at a weight ratio of about 5:1 to about 3:1.
7. The composition of claim 1 wherein water is contained in the cellular matrix at a concentration of about 10 to about 35% by weight.
8. The composition of claim 3 wherein the starch is incorporated in the cellular matrix at a concentration of about 30 to about 60% by weight.
9. The composition of claim 3 wherein the starch is wheat starch.
10. The composition of claim 4 wherein the proteinaceous binder is incorporated in the product at a concentration of about 5 to about 20% by weight.
11. The composition of claim 5 wherein the pyrophosphate salt is incorporated in the product at a concentration of about 0.5 to about 15% by weight.
12. The composition of claim 1 wherein a humectant is incorporated in the product at a concentration of about 1 to about 15% by weight.
13. The composition of claim 12 wherein the humectant is glycerin.
14. The composition of claim 2 wherein a synthetic anionic linear polymeric polycarboxylate is incorporated therein.
15. The composition of claim 14 wherein the polycarboxylate is a copolymer of maleic anhydride or acid and methoxyethylene.

16. The composition of claim 15 wherein the polycarboxylate is incorporated in the composition at a concentration of about 0.25 to about 4% by weight.

17. A method of removing plaque, tartar and stain from the teeth of an animal which comprises feeding the animal an edible, chewable, flexible unbaked extrudate product having a cellular matrix, the cellular matrix having incorporated therein of an effective mechanical cleansing amount of a cellulosic fibrous material, water to adjust the moisture concentration equal to or greater than 12% by weight and a humectant at a concentration of about 1 to about 15% by weight, said moisture imparting flexibility to the composition and retaining moisture so as to maintain the texture when the composition is stored and the animal chewing product.

18. The method of claim 17 wherein there is incorporated in the cellular matrix a pyrophosphate salt tartar control oral care additive, the ingredients forming the cellular matrix being substantially inert to the oral care agent.

19. The method of claim 17 wherein the cellular matrix is comprised of a starch.

20. The method of claim 17 wherein the cellular matrix contains a proteinaceous binder.

21. The method of claim 18 wherein the oral care additive is an alkali metal pyrophosphate salt.

22. The method of claim 21 wherein the alkali metal pyrophosphate salt is a mixture of potassium and so-

dium pyrophosphates at a weight ratio of about 5:1 to about 3:1.

23. The method of claim 17 wherein water is contained in the cellular matrix at a concentration of about 10 to about 35% by weight.

24. The method of claim 19 wherein the starch is incorporated in the cellular matrix at a concentration of about 30 to about 60% by weight.

25. The method of claim 19 wherein the starch is wheat starch.

26. The method of claim 20 wherein the proteinaceous binder is incorporated in the product at a concentration of about 5 to about 20% by weight.

27. The method of claim 21 wherein the pyrophosphate salt is incorporated in the product at a concentration of about 0.5 to about 15% by weight.

28. The method of claim 17 wherein a humectant is incorporated in the product at a concentration of about 1 to about 15% by weight.

29. The method of claim 28 wherein the humectant is glycerin.

30. The method of claim 17 wherein a synthetic anionic linear polymeric polycarboxylate is incorporated therein.

25 31. The method of claim 30 wherein the polycarboxylate is a copolymer of maleic anhydride or acid and methoxyethylene.

32. The method of claim 30 wherein the polycarboxylate is incorporated in the product at a concentration of about 0.25 to about 4% by weight.

\* \* \* \* \*

Exhibit D



## UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/154,646 USA/154,646	09/17/98	CLUEP	897-2391

EXAMINER	
HENDRICKS, K	
ART UNIT	PAPER NUMBER

1761 13

DATE MAILED:

03/09/01

*Below is a communication from the EXAMINER in charge of this application***COMMISSIONER OF PATENTS AND TRADEMARKS****ADVISORY ACTION** **THE PERIOD FOR RESPONSE:**

a)  is extended to run \_\_\_\_\_ or continues to run 3 months from the date of the final rejection

b)  expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

Appellant's Brief is due in accordance with 37 CFR 1.192(a).

Applicant's response to the final rejection, filed 2-23-01 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

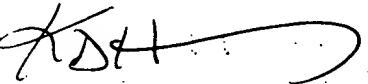
1.  The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
  - a.  There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
  - b.  They raise new issues that would require further consideration and/or search. (See Note).
  - c.  They raise the issue of new matter. (See Note).
  - d.  They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

Art Unit: 1761

**Attachment to Advisory Action**

The request for reconsideration does not overcome the rejections for the reasons of record, which clearly and specifically point out how each and every element of the rejected claims have been met. Applicants have completely ignored, and thus have not addressed, specific statements in the Final Office action regarding these points. For example, (1) At the top of page 4, regarding fiber content, and (2) referred to at the bottom of page 4, quoting Simone et al. At col. 5, lines 65-68, Simone et al. state that after extruding, "the chew particles are then allowed to cool and dry at a controlled temperature... to adjust the moisture level to about 10 to about 30% by weight" (underlining added). Applicants' arguments are incorrect, and misconstrue the reference, regarding the "final product" versus the extrudate at some point recently after extrusion.

Regarding the issue of "at least 2%", this is improper, and the rejection is maintained for the reasons of record. Applicants state that since they also disclose "insoluble fiber" as a general component without percent limitations, this naturally encompasses "at least 2%", and that "the claims as filed supported the use of any amount of insoluble fiber" (page 2 of response). This is improper. Initially, there is no support to select or define "2%" from "about 2%", in applicants' previous claims (certain of applicants' claims recite "about 2% to about 15%"). Secondly, there is no support for any and all percentages above the recited (about) 15%. For example, in instant claim 1, other than the improperly-added insoluble fiber component percentage (and a moisture level percentage, which is not a specific individual component, *per se*, but may be inherently provided by any component(s) including the insoluble fiber), there are no other percentages provided for the remaining components. Thus, according to applicants' arguments to "any amount of insoluble fiber" (presumably of "at least 2%"), the claimed pet food composition would encompass 80%, 90% or even 100% insoluble fiber. If this is the interpretation applicants contend, then the claims would still be improper, as it would be unclear as to how the remaining recited components could be present, if the composition was comprised of 100% insoluble fiber. If applicants wish to argue that the other components must be present as claimed, and therefore 100% insoluble fiber would obviously not be encompassed by the claim(s), then it would be unclear as to what percentages would be necessary for each and every component, including the insoluble fiber, from the broadly-recited claim(s). This would also conflict with several dependent claims, as well. Therefore, applicants' specification does not support the improperly-added phrase of "at least 2%".



KEITH HENDRICKS  
PRIMARY EXAMINER

Exhibit E



106  
UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/154,646 09/17/98 CUPP

*Thru*  
C P97-2391

IM22/0815

EXAMINER

HILL & SIMPSON  
A PROFESSIONAL CORPORATION  
85TH FLOOR SEARS TOWER  
CHICAGO IL 60606

HENDRICKS, K

ART UNIT	PAPER NUMBER
----------	--------------

1761

8

DATE MAILED:

08/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.	09/154,646	Applicant(s)
Examiner		Group Art Unit 1741

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- Responsive to communication(s) filed on \_\_\_\_\_.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- Claim(s) 1-24 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 1-24 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
  - received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). 6  Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

Art Unit: 1761

## **DETAILED ACTION**

### ***Allowable Subject Matter***

Applicant is advised that the Notice of Allowance mailed January 3, 2000, is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a Deposit Account.

Prosecution on the merits of this application is reopened. The indicated allowability of claims 1-24 is withdrawn in view of the newly discovered reference(s) to Gelfman. Rejections based on the newly cited reference, as well as others previously of record, follow.

It is noted that these references and impending rejections were discussed with applicants' representative on May 22, 2000, as well as suggestions for amending the claims, but did not result in an agreement at that time.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1761

Claims 1-3, 6-7, 13-15 and 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelfman et al.

Gelfman et al. disclose a dry soft canine biscuit comprising a denatured/gelled protein source and carbohydrate source (farinaceous and/or vegetable material), with insoluble fiber and about 5-15% of a humectant, including glycerin (col.'s 7-8). The denaturization and gelling is formed from the heat during extrusion. The final biscuit pieces have a moisture content of "less than or equal to about 15 percent by weight and preferably about 10 to about 12 percent by weight" (col. 9, lines 39-43). "The extruder material is cut into pieces or particles of [sic] having a diameter or granulation of between about 1/8 inch [3.17 mm] and about 1/2 inch [12.7 mm], preferably 3/16 inch" (col. 12, lines 19-23). At column 12, the reference states that when the composition contains vegetable protein to replace some or all of the meat protein, the product will have "a bulk density of about 15 to about 20 lbs. per cubic foot", which equates to 240-320 kg/m<sup>3</sup> (instant claims 6, 18). Insoluble fiber is not specifically mentioned as an ingredient; however, the farinaceous materials described at column 10 naturally contain some amount of fiber. For example, wheat generally contains 2.3- 5.6% total dietary fiber, with 1.7% of that insoluble, including cellulose. Corn flour has 15% insoluble fiber, including cellulose. (pg. 481, 484. Lorenz et al. "Handbook of Cereal Science and Technology", Dekker Press, 1991). Although this does not reach the threshold of "about 2% to about 15%" (instant claims 4-5,8-12,16-17), the instantly-rejected claims are anticipated by the reference. The recitation of the phrase "in the form of a cat kibble" is given little patentable weight, especially given the further description of this phrase in the claims as simple terms of measurements.

Claims 1-20 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Simone et al.

Simone et al. disclose an edible pet food product comprising a matrix which comprises cellulose (insoluble) fiber, gelatinized starch and protein components (see col. 3), and a humectant

Art Unit: 1761

such as glycerin at a concentration of about 1 to 15% (col. 5). The dried sections of this product were then subdivided into pieces which were 2.75 inch in length, 1 inch wide, and .25 inch thick, for the final product (col. 8). This product is formulated for administration to a pet animal. Thus, the claimed method is anticipated by the reference, as the claim recites measurements of "at least 6 mm". Simone et al. also teach that the cellulosic fiber materials of the pet food are used in the range of about 20-50% by weight of the final product (i.e. cellulosic materials such as corn cob, etc., not necessarily cellulose levels of 20-50%). Both wheat and corn sources are also used as the starch. Given that wheat generally contains 2.3- 5.6% total dietary fiber, with 1.7% of that insoluble, including cellulose, and corn flour has 15% insoluble fiber, including cellulose, (pg. 481, 484. Lorenz et al. "Handbook of Cereal Science and Technology", Dekker Press, 1991), and used in the amounts provided, this would be expected to give the product a cellose, and/or other insoluble fiber, level within the range instantly claimed. A density rating is not provided, however, given the fact that the remaining reference teachings fall within the boundaries of the instant claims, one of ordinary skill in the art would expect this to be an inherent property of the product. Finally, contrary to applicants' arguments in paper #6 of 12-17-99, Simone et al. teach that the moisture content of the final product can be dried "to adjust the moisture level to about 10 to about 30% by weight" (bottom of column 5, col. 7, lines 19 and 27 as "dried" thereafter). The recitation of the phrase "in the form of a cat kibble" is given little patentable weight, especially given the further description of this phrase in the claims as simple terms of measurements.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Hand et al.

Hand et al. teach of a chewy dry pet food, which is in the form of pellets, for both cats and dogs (col. 1). The product comprises a cohesive structural matrix containing proteins, starches, carbohydrates and fiber such as cellulose (col. 5). The starch is gelatinized ("plasticized"). The dried pellets thus produced have a moisture level of about 5-11% (col. 2, col. 7-8). At column 5, the reference states that the product may be in any of several shapes, and is preferred as a disc-

Art Unit: 1761

shaped pellet having a thickness of about 0.32 to 0.70 inch (about 8mm to 17mm), and the example product was cut into about 12mm (0.5 inch) thick pellets to be consumed by a dog. Finally, the product has a density ranging from "about 10 to about 35 lbs/ft<sup>3</sup>" (160 to 560 kg/m<sup>3</sup>). Hand et al. does not teach the use of a humectant.

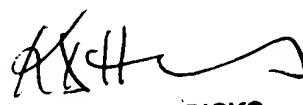
### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gabrielle Brouillette, can be reached at (703) 308-0756. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
KEITH HENDRICKS

PRIMARY EXAMINER

  
Jerome W. Morris  
Director (Acting)  
Technology Center 1700

37 CFR 1.501  
**INFORMATION DISCLOSURE STATEMENT**  
 IN A PATENT  
 (use several sheets if necessary)

Docket No. P97,2391 Serial No. 09/154,646

Applicant  
 Cupp et al.

Filing Date  
 September 17, 1998 Group Art Unit  
 1761

**U.S. PATENT DOCUMENTS**

Examiner's Initials		Document Number	Date	Name	Class	Subclass	Filing Date If appropriate
<i>BB</i>	AA	4,006,266	2/1/77	Bone et al.	426	623	
	AB	4,364,925	12/21/82	Fisher	424	50	
	AC	4,743,460	5/10/88	Gellman et al.	426	549	
<i>duplicate</i>	<i>AD</i>	<i>5,407,661</i>	<i>4/18/95</i>	<i>Simone et al.</i>	<i>426</i>	<i>809</i>	
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

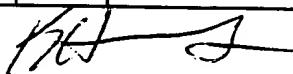
**FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
<i>BB</i>	AL 01 039953	2/10/89	Japan				
<i>BB</i>	AM 0 645 095 A1	3-29-95	Europe				
	AN						
	AO						
	AP						

**OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)**

AQ	
AR	
AS	
AT	

Examiner



Date Considered



**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.